

Acupuncture in health care –

Attitudes to, and experience with acupuncture in Norway

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Preface

My work in health care started in 1981 at Harstad hospital as a nurse assistant. I very soon found out that caring for, nursing and treating patients was my future field of interest. When I finished my nursing studies in 1986, my eagerness to learn more gave me the energy to proceed.

In the following years, it became clear to me that I simply had to materialize my old dream of studying medicine. I therefore felt delighted when I started my medical studies at the University of Tromsø in 1990. I can still remember how proud and satisfied I felt becoming a doctor in 1996.

But, I also wanted to do something different, and I had been “looking upstream” for some period of time. Alternative medicine challenged my curiosity, and acupuncture therapy has fascinated me for two decades. How insertion of needles can alleviate pain and help people in their struggle against diseases was, and still is, mysterious and most interesting.

In the years 1987-1990 I attended various acupuncture courses in Norway and Sweden, and I stayed for a period in Beijing, China. I also published my first book;” This is what you should know about acupuncture”, and gained acquaintances with central persons within the Norwegian acupuncture community.

Through the years, the “acupuncture movement” has consisted of a heterogeneous group of people with different intentions, motives and beliefs. I have always been interested in who became acupuncture patients and how these patients are taken care of in the healing process.

When students in the second year of medical studies at the University of Tromsø were encouraged to participate in research, it therefore became natural for me to investigate attitudes to and experience with acupuncture. The easiest thing was to start with my fellow students at the University.

My first scientific paper in the Journal of the Norwegian Medical Association inspired me. In the years to come information about attitudes to and experience with acupuncture was also collected from doctors, patients, and acupuncturists. A clinical double- blind placebo-controlled study on acupressure for morning sickness in early pregnancy was also performed. During these years, I realised that a doctoral thesis was within reach sometime in the future.

The question now is what’s next?

I feel satisfied when finishing a project started ten years ago. The eagerness to learn more has been the internal force giving me the energy to overcome all this work and struggle. I am now ready to use some of my energy in other positions, and perhaps my scientific knowledge and experience can be useful for other people who want to materialise their wishes and dreams regarding scientific work??

Acknowledgements

There are many persons who have inspired me and encouraged me in my work with my final thesis. However, the far most important person is professor Vinjar Fønnebø who has been my supervisor and guided me from the time I was a medical student and up to the completion of my final thesis. He has this special capability of setting very high standards for the scientific work that takes the breath from you in the beginning, but at the same time, he makes you believe that you can really “get there”.

During the last four years of medical studies 1992-96, I was affiliated with the Institute of Community Medicine at the University of Tromsø. Many ideas and results were discussed with many interested and encouraging people; no one mentioned, no one forgotten.

I would, however, especially like to thank secretary Gerd Furumo for her assistance with the questionnaires when collecting the data. Helpful assistance from the computing unit at the Norwegian Medical Association, the acupuncture associations and the National Population Register provided the samples needed for the surveys.

I would also like to thank my fellow student, colleague and friend Erik Jesman Pedersen for his support and advice. Other friends have also helped me, and the hours around the kitchen table, folding questionnaires and putting them in envelopes will not be forgotten.

Cooperation with allied partners within the acupuncture community has been very important in my work. I have been lucky to cooperate with many other acupuncture researchers in Norway. Helpful advice, meaningful and important discussions have been useful all the way.

Professor Christian Borchgrevink who initiated research in alternative medicine more than a decade ago gave me early inspiration. He had a leading position when research was introduced in alternative medicine in Norway and might be considered the godfather of the alternative medicine research programme in the Norwegian research council.

Dr Dag Eivind Syverstad was the person to continue the investigations on attitudes to and experience with acupuncture among medical students in Tromsø. In cooperation with him, we were able to demonstrate the important changes in attitudes to acupuncture during medical studies and the probable impact of role models.

I would also like to thank the Norwegian research council for their financial support. I have received student scholarships for the surveys of attitudes of acupuncture among doctors, acupuncturists and in the general population as well as for the study on acupressure for morning sickness. Finally the research council also supported me with a scholarship during my writing of the final thesis while staying in New Zealand. Torbjørg Øyslebø has been especially helpful through all the application processes.

I am also very thankful to my friend, chief surgeon and associate professor Børge Ytterstad for support and advice. Not only on the work with my final thesis, but he also contributed to my stay at the University of Auckland in New Zealand. While staying in their lovely country “down-under”, a lot of friends and colleagues at the Department of Community Health at the Faculty of Medicine, University of Auckland gave me helpful advice and support.

Last but not least, I am deeply indebted to my wife Tove, and my two children Marita and Tor-Johan for their patience, encouragement and sacrifice during the work with my final thesis. The scientific work has been my “hobby and passion”, and some of all the hours in front of my computer could definitely have been spent otherwise.....

List of papers

I.

Norheim AJ, Fønnebø V. Doctors attitudes to acupuncture and their experience as acupuncture patients - A Norwegian study. Soc Sci Med 1998;47:519-23.

II.

Syverstad DE, Norheim AJ, Fønnebø V. Changes in medical students' attitudes towards acupuncture: The possible impact of role models. Education for Health 1999;12:195-201.

III.

Norheim AJ, Pedersen AJ, Fønnebø V, Berge L. Acupressure for morning sickness in pregnancy - A randomised, double-blind, placebo-controlled study. Scand J Prim Health Care 2001;19:43-7.

IV.

Norheim AJ, Fønnebø V. Acupuncture patients in Norway - Results from a questionnaire among a random sample in the general population. Compl Ther Med 2000;8:87-92.

V.

Norheim AJ, Fønnebø V. Attitudes to the contribution of placebo in acupuncture – a survey. Compl Ther Med 2002;10:202-9.

The papers will be referred to by their Roman numerals in the text

Definition of terms used in the thesis

Traditional Chinese Medicine (TCM)=A system of diagnoses and therapeutic measures derived from ancient Chinese tradition and empirical observations. TCM consists of several different approaches like internal and external pharmacological therapy, acupuncture stimulation, Chinese massage, dietary and lifestyle advice, physical exercise and movement, Orthopaedic manipulation and lots of other techniques like moxibustion, cupping, scraping and point injection therapy.

Acupuncture point = certain defined areas/points on body surface for diagnostic and therapeutic purposes according to the ancient TCM-theories. The classical 365 points are found on the 12 main and the eight extra channels. In addition, numerous tender points or trigger points are regarded as acupuncture points because acupuncture theories hold that “wherever there is pain, energy is stagnant, and the stagnation can be moved by an acupuncture needle”.

Acupuncture = a method of inserting special needles into acupuncture points on the body to treat disease and alleviate pain or produce analgesia. Acupuncture can be practiced according to the ancient Chinese theories, while some acupuncturists use recipes or plain trigger-point-acupuncture.

Acupressure = Pinching or pressing at acupuncture points. Most commonly finger pressure is exerted, but wristbands or other remedies can exercise the pressure.

Unconventional medicine =Alternative medicine= Diagnostic and/or therapeutic systems outside the ordinary health care system. Alternative medicine is principally based on empirical data.

Conventional medicine = Diagnostic and/or therapeutic possibilities within the ordinary health care system. Conventional medicine is principally based on randomised clinical trials, clinical practice, and is held to be evidence-based.

Summary

Introduction

Acupuncture is a part of Traditional Chinese Medicine, one of the oldest medical systems in the world. This web of rather foreign thinking is based on theories about the five elements, the Chinese organ system, and the fundamental substances in the human organism. While new conventional medical interventions are primarily evidence-based, unconventional therapies like acupuncture has already existed a long time as a treatment option. Research in acupuncture has only just begun.

Little is documented concerning channels and acupuncture points, but the effect of acupuncture on certain conditions is considered fairly well documented even though adverse effects might be inevitable. Attitudes to acupuncture seem in general to have become less negative, and both the youngest doctors and the population in general seem to regard acupuncture as a realistic alternative to conventional health care for certain conditions.

The aim of the present study is therefore to describe the position and role of acupuncture in terms of attitudes to and experience with acupuncture among medical students, doctors and within the general population.

Materials and methods

From February 1994 to June 1995 anonymous questionnaires were distributed among 1466 randomly selected doctors, 354 medical students, 605 acupuncturists and a random sample of 1100 persons in the general population of Norway. The response rates obtained were 77% for the doctors, 83% for the medical students, 71% for the acupuncturists and 61% in the general population. The questionnaires were returned in a pre-addressed, stamped envelope.

All questionnaires included questions concerning having tried and/or willingness to try acupuncture, attitudes to placebo in acupuncture, attitudes to the use of acupuncture in migraine and cancer, and attitudes to the integration of acupuncture into conventional medicine. They were also asked about their familiarity with acupuncture adverse effects.

The clinical study on acupressure for morning sickness in pregnancy was carried out from January 1995 to March 1996. Ninety-seven pregnant women participated for 12 days: a four-day run-in, a four-day intervention, and a four-day follow-up period. Symptoms of nausea and vomiting were recorded daily during this 12-day period. Participants were asked to make three recordings of their problems every evening.

In all the surveys a conventional significance level of 0,05 and a power of 0,80 was chosen. The statistical analyses were done utilising the chi-square test, Fischer's exact test, and two-sample t-test. Adjustments were done by the Mantel-Haenschel method for stratified data. The computer software used was EPI-INFO.

Results

Eight percent of the doctors had undergone acupuncture treatment, and 53% would consider acupuncture if they developed a problem or disease where acupuncture could be an alternative. More than 38% of the doctors recommend acupuncture treatment to their migraine patients. More than four out of five doctors would not try to interfere with a patient's wish to try acupuncture treatment for cancer.

Medical students change their attitudes in a more negative direction as they approach the end of medical school. A higher proportion of students in their fifth and sixth year would not consider acupuncture if they had complaints or diseases where acupuncture could be an alternative compared to when they were in their first and second year (13,7% versus 4,0%, $p=0.03$). A higher proportion would also actively advise their future migraine patients against acupuncture treatment (13,7% versus 2,0%, $p=0.005$). When asked about what advice they would give to a future cancer patient, who they could not help with conventional medicine, a substantial higher proportion would discourage the patients (20,5% versus 6,0%, $p=0.008$) when they were in their fifth or sixth year.

One out of five in the general population, most often those suffering from musculo-skeletal pain, had tried acupuncture treatment for own disease. Sixty-six per cent of these indicated benefit from acupuncture treatment, while seven percent reported that the acupuncture treatment had adverse effects. Acupuncture patients visit their GP more often ($p<0.01$), and are more concerned about own health ($p<0.01$) than patients who have not tried acupuncture. The major part of the general population, and also medical doctors, has already undergone acupuncture or indicate that they would consider doing so. Use of acupuncture is associated with positive attitudes to the method.

Among all 2514 subjects in the study, 57% indicated the treatment effect seen in acupuncture to be mainly a genuine acupuncture effect, 30% indicated that half of the effect in acupuncture comes from placebo, while 13% indicated that the treatment effect in acupuncture is mainly a placebo effect. Among doctors, 39% indicated that the treatment effect in acupuncture was mainly due to a genuine acupuncture effect, while the proportions among medical students, the general population, and the acupuncturists are 47%, 74% and 84% respectively (all $p<0.001$)

In the clinical study of acupressure for morning sickness in pregnancy, the majority of the 97 participating women improved their symptoms of nausea and vomiting when using Acupressure Wrist Band (AWB) or Placebo Wrist Band (PWB). More women in the active group (AWB) responded positively, although a significance level of five percent was reached only with regard to duration of symptoms. The mean duration of symptoms (hours) was reduced 2.74 hours and 0.85 hours, respectively ($p=0.018$).

Discussion

Selection bias could have arisen both in choosing a sampling frame and in the response phase. In the questionnaire studies, minor changes in wording of the questions due to differing knowledge levels in the studied groups, had to be done. This could challenge content validity and the comparability of the results between the groups. Other sources of information bias

were minimized through piloting of the questionnaires before use and including questions previously used in other studies.

Keeping these possible sources of bias in mind, the present thesis gives reasonably valid information about attitudes to, and experience with acupuncture. An advantage of the present study is the direct focus on acupuncture, and not the study of acupuncture as a part of alternative medicine in general. Although a qualitative approach to a study on attitudes could have been chosen, the study protocol warranted a quantitative design.

In the clinical study of acupressure for morning sickness in early pregnancy, the methodology was improved in comparison with previous research. However, voluntary enrolment could give rise to selection bias. And further, self-reported measures of effect and recall problems could introduce information bias. The random allocation utilised was used to minimise information bias and confounding.

Conclusions

Unconventional therapies like acupuncture are widely available and commonly used by the public. According to a five-level research model, this thesis has described the position and role of acupuncture in terms of attitudes to and experience with the method among medical students, doctors and within the general population. Some data of level two regarding adverse effects are also included, and the clinical trial addresses issues at level four.

It is likely that acupuncture might play a substantial role in future healthcare, being a therapeutic option widely accepted by doctors and currently commonly used by the public. Bearing this in mind, the present thesis might contribute to the basic knowledge about attitudes, practice and experience with acupuncture, necessary for future political and medical decision-making.

1. Introduction

1.1. Ancient thoughts in Traditional Chinese Medicine

Traditional Chinese Medicine (TCM) is probably one of the oldest medical systems in the world. A variety of preventive as well as therapeutic measures constitute the web of TCM. Some of the techniques (cupping, bloodletting and herbal medicine) are the same as can be found in other practices of folk medicine worldwide. The Chinese energetic gymnastics like Tai Chi and Qi-gong have also been practiced in other parts of the Asian world for ages, but the systematic use of needles in acupuncture therapy seem to be a specific Chinese phenomenon.

The classic concepts in TCM are based on the philosophy of Taoism, which can be interpreted as “the way of nature”. To live with Tao means to live in harmony with the surrounding nature and environment, coping with the constant natural changes.

1.1.1. The yin-yang theory

One of the most important theories in TCM is the universal antagonism represented by the Yin-Yang theory. Water and fire are the main symbols of Yin and Yang. Water can be used to put out a fire, but some of the water will then disperse. This is an example of how Yin can consume Yang (water puts out the fire) but is then itself consumed (dispersion). This is called the inter-consuming-supporting and inter-transforming relation of Yin-Yang.



Figure 1:
The Chinese Yin-Yang symbol.

Yin means the shadow-side of the mountain, while Yang means the sunny side of the mountain. Yin then represents darkness, coldness and passivity, while Yang means light, warmth and activity. But within Yang there is Yin, and within Yin there is also some yang.

Every person should have a balance of Yin and Yang, and unbalanced yin-yang-energy leads to disease and complaints. A classic Yang-disease is hyperthyroidism. The patient's symptoms can be increased metabolism resulting in anxiety and nervousness with shivering hands, flushing, feeling of heat and rapid pulse. Hypothyroidism can conversely be regarded as a classic Yin-disease with fatigue, feeling of low energy, faulty memory and concentration, slow pulse and low blood pressure.

1.1.2. The five elements

Another basic thought in the Tao world is the theory of the five elements; Wood, Fire, Earth, Metal, and Water. Table 1 shows how the external nature and the human organism are connected in the theory of the five elements.

Table 1. The five-element theory in Chinese medicine.

	Nature					Human			
Element	Season	Development	Climate	Polarity	Colour	Taste	Sense organ	Tissue	Emotion
Wood	Spring	Germination	Wind	East	Green	Sour	Eye	Tendon	Anger
Fire	Summer	Growth	Heat	South	Red	Bitter	Tongue	Vessels	Joy
Earth	Indian summer	Ripening	Humidity	Centre	Yellow	Sweet	Mouth	Muscles	Worry
Metal	Autumn	Withering	Dryness	West	White	Tasty	Nose	Skin/hair	Longing
Water	Winter	Death	Cold	North	Black	Salt	Ear	Bones	Fear

As with the Yin-Yang phenomenon, there is an inter-promoting, over-acting, and counter-acting relation between the five elements. The elements are situated after each other in a five-star pattern in the below-indicated sequence (figure 2).

Processes in nature can be attributed to the elements, also the human organism, the internal organs, and even the emotions. An important concept in acupuncture is to restore harmony and the free flow of energy between the elements.

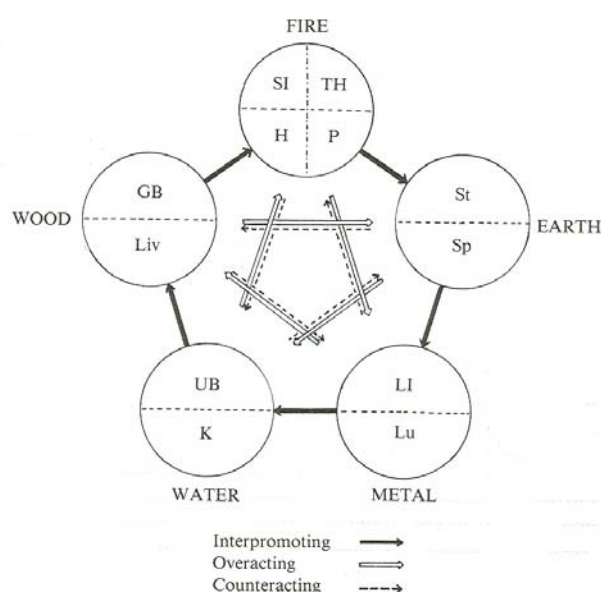


Figure 2.
The interaction of the five elements

One element promotes growth of the next element in the chain. This is called the “mother-son-relationship”. Further, the figure also shows how control is maintained among the elements. A Chinese saying says: “Without promotion of growth there would be no birth and development; without control excessive growth would result in harm.”

1.1.3. The organ system in TCM

In TCM the organs are called “ZANGFU”. The Chinese organ theory includes more than the morphological organs and their physiological functions. Emotions and specific energy flow are linked to certain organs, and pairs of organs are directly attributed to each of the five elements (figure 2).

The ZANG-organs are all solid and their main function is to manufacture and store essential substances including vital essence, vital energy, blood and body fluids. The ZANG-organs are: heart, liver, spleen, kidney, lung and pericardium. Each ZANG-organ is also related to a FU-organ.

The FU-organs’ main functions are to receive and digest food, absorb nutrient substances, and transmit and excrete wastes. The FU-organs are: stomach, small intestine, large intestine, gallbladder, urinary bladder and the *sanjiao*. The *sanjiao* is not an anatomical organ, but more a generalization of body-functions within three sections of the organism: chest, epigastrium and hypogastrium. There are in addition extraordinary FU-organs, including the brain and uterus.

1.1.4. The fundamental substances in the human organism

To sustain normal vital activities in the body the fundamental substances Qi, blood and body fluids are of importance. Their existence and function, especially those of Qi, are generally manifest in the functional activities of various tissues and organs. The flow of Qi can be compared to the tide, in which every organ has a maximum and a minimum, and the circulation follows a 24-hour cycle (“the organ-clock”).

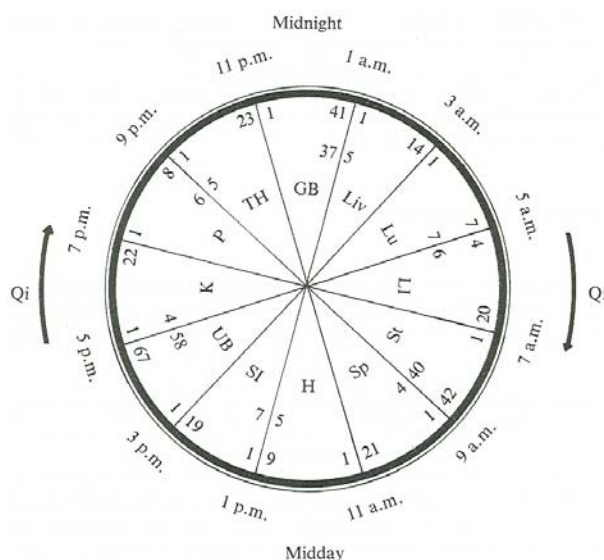


Figure 3.
The Chinese organ clock.

According to Chinese medicine the energy within the body flows like a tide. At a certain time each organ has its maximum and minimum of energy leaving it either strong and vital or weak and defenceless.

The direct translation of the term “Qi” (=chi) is: “The steam for boiling rice”. In Western culture and language, this has been translated to energy. The term energy, however, gives a limited understanding of the term, and in the human organism the Chinese define several

different Qi with different locations and functions. A Chinese saying says; “Qi is the foundation of life, birth and development”. In acupuncture, the manipulation of the needle should result in the so-called “De-Qi” which can be felt as a weak soreness, which the Chinese call “the arrival of Qi”.

1.1.5. The Channels and points in traditional Chinese acupuncture

Acupuncture channels and their collaterals are distributed throughout the human body, connecting the internal ZANGFU-organs with the body surface. Each of the 12 organs has its own channel with a specific distribution on the body surface. In some Chinese textbooks, the channels are called meridians like the meridians on the globe. An additional eight extra channels and 15 collaterals are defined within TCM, linking up the whole body to an organic integrity. In addition to the important “Qi-transport”, the channels have the function of maintaining body temperature and nourishing the tissues.

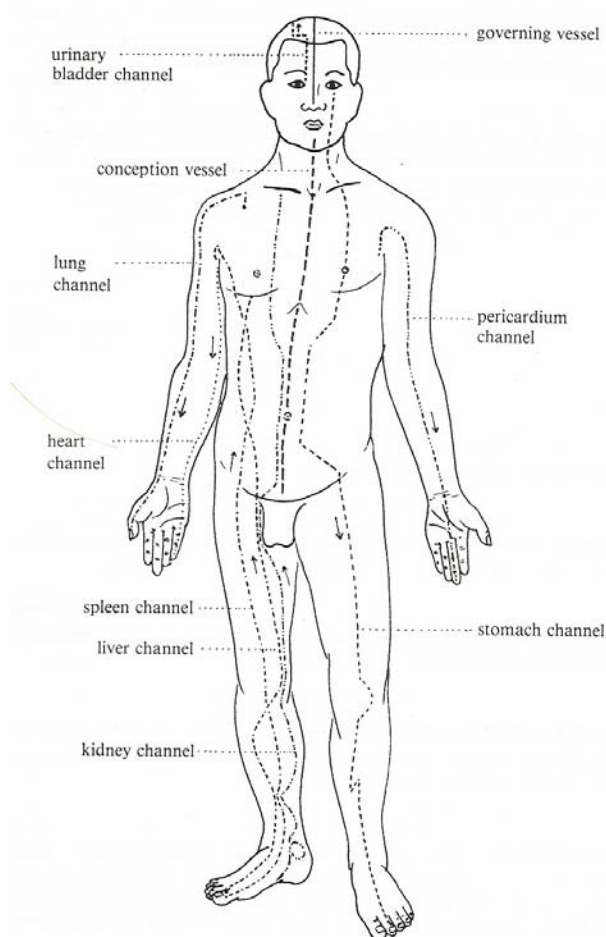


Figure 4.
The meridians in Chinese medicine

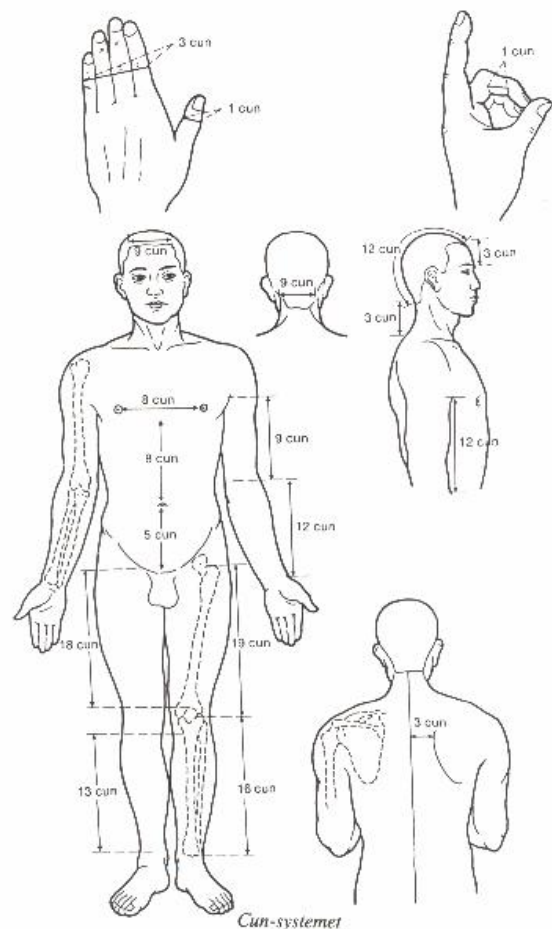


Figure 5.
Chinese acupuncture points and the cun measurement

Energy-points are situated along the channels, and these are called acupuncture points. The location of these points is described in the ancient literature of Traditional Chinese Medicine. A specific Chinese measurement called “cun”, along with anatomical landmarks, defines the position of each acupuncture point. One cun is the length of the middle part of the index finger.

The theory of channels and points is important for the understanding of pathogenesis and treatment principles in acupuncture therapy. Channels and points serve as a route in which pathogenic factors can attack the body. Likewise, to regain health, the point selection and type of stimulation is crucial. Most often a combination of local points adjacent to the affected area/organ is selected in addition to points on corresponding channels in other parts of the body. Acupuncture points can be stimulated using needling, pressure, heat or cupping.

1.1.6 Pathophysiology and diagnostics in TCM

Causes of disease in TCM are classified as external pathogenic factors (=climate), internal pathogenic factors (=emotions), and miscellaneous factors like f.i. worm-bites, burns, loss of blood, lifestyle and epidemics. These factors can influence on the cyclical and regular flow of energy (qi), and the other vital substances in the body. Whenever the free flow is hampered or obstructed, there will be symptoms and/or pain.

Diagnoses in TCM focus mainly on energetic aspects, and the crucial task is to find the underlying disturbance or cause of stagnation. One of the major ways to identify such disturbances is by taking the patient’s history, clinical examination including pulse and tongue diagnostics.

1.1.7. Summary and comments on classic ancient thoughts in TCM

Some practitioners of acupuncture enter the arena of needle therapy to “get a new start in their own life”. These individuals have a more or less religious relationship to TCM. This view and attitude can be mirrored in their way of practicing acupuncture. These practitioners seem to believe in Qi, Five elements, Channels and Points as real entities, and their approach to therapy using pulse and tongue diagnoses might for an uninitiated person seem to be a mysterious, and perhaps unbelievable, journey. Other acupuncturists, mainly Western medical doctors, use acupuncture in the same way as they use any other therapeutic remedy. Point selection is often based on “cookbook” prescriptions, or a point combination they have learned in a short acupuncture course. Others only insert needles in the painful areas of the body or directly into the patient’s trigger points. Some in this latter group of “western-medical-acupuncturists” more or less deny the existence of the ancient Chinese acupuncture theories.

Even those who have practiced acupuncture for years might find it difficult to grasp the meaning of Qi, and the morphological correspondence to channels and points is hard to find. The Yin-Yang- and five-element theories are part of the ancient Chinese philosophy, and cannot be directly amalgamated into Western culture and understanding. In addition, a very different understanding of disease aetiology among TCM practitioners compared to “Western” doctors makes it rather difficult to translate the theories of acupuncture into an understandable Western medical paradigm. For the patient, however, a TCM-based explanation of their disease can easily make sense. Explaining that nausea and vomiting is due

to stomach energy turning upwards instead of the normal downward direction can give a more understandable explanation for the patient than Western medical theories. It might therefore be important to accept the ancient Chinese terms as part of a useful vocabulary.

1.2. The history of acupuncture

1.2.1. Acupuncture in China

Archaeological findings dating back 8-10 000 years tell us that acupuncture-like methods were used in the Stone Age. In the beginning, the needles were made of bones and sharp stones, but from the Bronze Age onwards needles were made of metal. The oldest written material that has been discovered is dated to about 2000 B.C.

The fundamental reference in TCM “Huang Di Nei Jing” (The Yellow emperor’s book of internal medicine) was probably written over a period of 200 years. The book describes mainly a discussion between the emperor and his doctors. In the book, all the ancient theories of acupuncture are discussed as well as some basic thoughts on Tao philosophy. The theories of the five-elements, Yin-Yang and the Channel-system are the same as can be found in Chinese TCM literature today.

Today’s acupuncture therapy has developed over a period of more than 3000 years. The theories became more sophisticated, and the technique of needle stimulation and point-combination more advanced. During the Ming-dynasty (1368-1644) the development had reached a peak.

Over the next 300 years, however, the development turned into total stagnation, and acupuncture was even in periods forbidden by the authorities. Western countries started to colonize the Far East, and after the Opium-war in 1840, the Chinese government wanted to replace acupuncture with Western medicine.

In the period of the civil war in the 1940s, acupuncture once again became popular. There was a need for medical measures against epidemics and disease, and folk medicine was often the only choice. In addition, chairman Mao was aware of the potential of awakening traditions and old folks’ feeling of their roots. This encouraged them on their “long march”, and made chairman Mao even more popular among the people.

Over the last 50 years, acupuncture has become an important part of Chinese public health care. More than 30 medical faculties educate TCM doctors, and more than 500 000 currently practice acupuncture. In 1975, WHO encouraged Chinese authorities to establish an international acupuncture education centre. The first three were founded in Beijing, Shanghai and Nanjing where thousands of foreigners have been educated in acupuncture and TCM

In 1979 the first WHO-congress on acupuncture was held in Beijing working out a set of guidelines for education, indications, safety and research in acupuncture (WHO 1991, 1994, 1996). The interpretation of these guidelines has not resulted in a universal understanding, and therefore there is still a substantial difference in how acupuncture is practiced in China, the United States, Europe, and Norway.

The first international acupuncture association, The World Federation of Acupuncture and Moxibustion Societies (WFAS), was also established in Beijing under the influence of WHO. Several hundred acupuncture associations from more than 60 different countries are now members.

1.2.2. Acupuncture in Europe

Acupuncture was not practiced outside China until about 500 AD. Other countries in the Far East started to use acupuncture long before the method was introduced in the Western world.

Through trading, acupuncture was introduced to sailors, and the Dutch ship's doctor Wilhelm Ten Rhyne probably wrote the first Western book on acupuncture in 1683. As French Jesuits established missions among the Chinese people, they experienced people being cured from disease by needle therapy. During the next 300 years the method became known in Europe, but the willingness to use the method was rather low. However, it is interesting to note a Swedish thesis in acupuncture from 1829 (Landgren, 1829).

It was not until the ancient Chinese literature in acupuncture was available that acupuncture became more popular in Europe. The French diplomat Souliè de Morants translated "Huang Di Nei Jing" in 1929. This translation is regarded as epoch-making for the practice of acupuncture in Europe. From France the method spread to Germany, and from 1950 an increasing number of Europeans visited China to learn the method.

Around 1970 the stories of acupuncture used as an anaesthetic during surgery initiated renewed interest for the method. A sizeable number of medical personnel travelled to China to have a look at this extraordinary phenomenon. During the last 30 years, several educational centres and associations have been founded. From around 1990, research centres in England and Germany have been in the forefront of research in acupuncture.

1.2.3. Acupuncture in Norway

Folk medicine and alternative medicine has previously been partly regulated in Norway through the Medical Quackery Act of 1936. The prescription of drugs, surgical intervention, injection and complete or local anaesthesia were procedures restricted to doctors and dentists. There was an unresolved issue whether acupuncture should be classified as a surgical intervention under the Medical Quackery Act, but under new legislation in place from January 1. 2004, no treatment procedures are singled out to be exclusively used by certain professions.

In Norway, acupuncture was introduced around 1970. The two doctors Georg Bentze and Vilhelm Scheldrup brought the ideas from Central Europe to our part of the continent. The first Norwegian book on acupuncture, "Medicine on new roads", by Dr Scheldrup came in 1974. In 1972, a group of Norwegian doctors led by professor in neurophysiology Birger Kaada visited China to acquire a broader look at acupuncture (Kaada, 1974). Since then, professor Kaada has continued to explain the effect of acupuncture in Western medical terms and theories (Kaada, 1982a; Kaada, 1982b; Kaada, 1986; Kaada, 1989).

Until 1980, most Norwegian acupuncturists were trained at the International College of Oriental Medicine (ICOM) in England. Some were also educated in Germany, France and Sweden, while a few learned the method in China. Since 1980 several Norwegian acupuncture schools have opened, and today those who want to learn the method can choose between several acupuncture educational institutions in the country. Most of these are concentrated in the Oslo area, and run on a private basis. The content and duration of the education and the entrance requirements vary widely, leaving acupuncture practitioners with varying knowledge, skills and attitudes.

In 1978 the Norwegian Association of Classical Acupuncture was founded and Norwegian Main Association of Acupuncturists was established in 1995. Norwegian doctors established their own association in 1980, and around 500 Norwegian doctors have attended acupuncture-training courses. In 1990, the Norwegian Medical Association (NMA) established its own acupuncture committee, and the central board in the NMA voted to continue their interest and engagement in alternative medicine. The acupuncture committee has further suggested that all physicians should actively try to learn and practice acupuncture (Acupuncture committee in NMA, 1992), but some members disagree.

The Norwegian Research Council has supported Norwegian acupuncture research since 1993. The aim of the alternative medicine programme in the Norwegian Research Council was to stimulate research of high quality, and to encourage alternative practitioners to learn more about research methodology. Today the Norwegian Research Council evaluates research grant proposals in acupuncture together with other clinical research grant proposals.

After a unanimous request by the Norwegian parliament, the Ministry of Health and Social Affairs in April 1997 appointed a committee, led by professor Jarle Aarbakke, to report on various aspects of alternative medicine. In December 1998 the report was handed over to the ministry of Health and Social Affairs (NOU, 1998:21). The committee considered the acupuncture treatment effect to be documented on certain indications (see section 1.3.3).

In accordance with the proposal from the Aarbakke committee, a centre for alternative medicine research was established at the University of Tromsø in August 2000. The National Research Center on Complementary and Alternative Medicine (NAFKAM) is an independent unit under The Faculty of Medicine. The objectives of the centre are to give an understanding of how alternative medicine can contribute to reducing or diminishing disease and complaints in the population. This should be done through education, supervision and network building, but the main activity should be to supervise and support research in alternative medicine. Acupuncture is together with homeopathy the main alternative technique to be investigated, both in terms of effect, but also attitudes to the methods as such.

Several international conferences on acupuncture have been held in Norway, and Norwegian acupuncturists and researchers have given a broad presentation of their research. The last WFAS-conference held in Oslo in September 2003 had more than 300 representatives from 20 countries.

1.2.3.1. Practice of acupuncture in Norway today

The exact number of acupuncturists in Norway is difficult to estimate. According to the results of a 1997 survey performed by the Aarbakke committee, approximately 550 acupuncturists have been educated at Norwegian educational institutions up to July 1997 (NOU, 1998:21). In addition to these, approximately 500 doctors and physiotherapists had participated in "Norwegian Doctors' Acupuncture Training Course" (NDATC) (Norheim, 1995, unpublished data). And finally, an unknown number of practitioners have their background from educational institutions in other European countries and China.

It seems reasonable to estimate that at least 1500 persons have been educated in acupuncture up to the year 2000. At least 15-20% of those who once were trained in the method have,

however, stopped practicing due to economical, practical or professional reasons (Aanjesen, 2002).

The majority of acupuncturists are men under 45, half of them live in the Oslo area, and 80% have a previous health-profession education (Norheim, 1995-unpublished data; Sagli, 1998). One Norwegian hospital-based pain clinic has utilised acupuncture for more than a decade (Norheim, 1990), and today acupuncture is practiced at several outpatient public pain clinics in 19% of Norwegian hospitals (Salomonsen, 2003).

In a survey among all Norwegian acupuncturists found in the yellow pages of the telephone directory and all previous participants of Norwegian Doctors Acupuncture Training Centre (NDATC) the participants were asked about how they practiced acupuncture (Norheim, 1995-unpublished data). Most acupuncturists educated at NDATC are not found on the yellow pages, and they are educated according to a Western way of practicing acupuncture. Results from the questionnaire are presented in table 2.

Table 2. Background and practice among 197 acupuncturists found on the yellow pages of the telephone- directory, and 235 acupuncturists educated at “Norwegian Doctors Acupuncture Training Course” (Norheim, 1995-unpublished data)

	Acupuncturists found in the yellow pages in the telephone directory (95% CI)	Acupuncturists trained at Norwegian Doctors Acupuncture Training Course (95% CI)	P-value
Annual number of acupuncture patients (Number)	654 (529-781)	123 (85-173)	P<0.001
Duration of acupuncture consultation (Minutes)	48 (46-50)	34 (31-37)	P<0.001
Cost of acupuncture consultation (NOK)	198 (193-203)	132 (125-139)	P<0.001
Have tried acupuncture for own disease (Percent of responders)	76,8 (72,0-81,6)	24,4 (21,4-26,6)	P<0.001
Have encountered acupuncture adverse effects in practice (Percent of responders)	52,3 (45,0-59,6)	55,0 (48,9-61,1)	P=0,154

Mean duration of practice for all acupuncturists was 4,5 years. Acupuncturists educated at NDATC have fewer acupuncture patients; have shorter acupuncture consultations at a lower cost than acupuncturists listed on the yellow pages (all p<0,001). Acupuncturists listed on the yellow pages also have more often tried acupuncture for own disease (p<0,001). There is little

difference in experience with acupuncture adverse effects between the two groups of acupuncturists.

Although acupuncture has been available on a large scale in Norway only in the latest 10 years, the mean annual number of acupuncture patients per population unit in 1995 seems low compared to Europe (Fulder 1985) and the United States (Eisenberg 1993). There is approximately one acupuncturist per 4-5000 inhabitants, and 19% of the Norwegian adult population has tried acupuncture for own disease. The typical Norwegian acupuncture patient is a woman aged 30-40 suffering from headache or muscular-skeletal pain. The pattern of acupuncture use, and the characteristics of Norwegian acupuncture patients are presented in this thesis (Paper IV).

1.3. Research in Acupuncture

The history of scientific research in acupuncture has a duration of only a few decades. The skills and knowledge, however, have been upheld for thousands of years by word of mouth and thoroughly recorded practice. Acupuncture is therefore mainly based on empirical knowledge, and there still seems a way to go before acupuncture can be regarded as evidence-based medicine.

Despite this lack of scientific basis, acupuncture is widely used throughout the world. Users of the method, both patients and practitioners, are interested in a thorough understanding of the method and information about the safety aspect in addition to the scientific evidence of effect and knowledge about the mechanisms behind the specific acupuncture effect.

Acupuncture has been investigated through extensive research throughout the world. Some of the recent knowledge has been presented in several systematic reviews published during the last decade. These syntheses of knowledge have been regarded as the best evidence for clinical decisions (Cook, 1997). But how objective are systematic reviews in alternative medicine (Linde, 2003b)? Could it be that the nature of acupuncture and the methodological challenges in this kind of research hampers the understanding of acupuncture? Could it be that a scientific presentation of acupuncture should be presented according to a new agenda?

Keeping all these ideas in mind, research in acupuncture could be subdivided into different levels of knowledge (<http://www.forskning.no/artikler/2003/november/1068819412.14>; Fønnebø, 2004)

1. The description of the method
2. The safety aspect in acupuncture therapy
3. The acupuncture “system-effect” in the therapeutic setting
4. The acupuncture “component effect” in therapy and clinical trials
5. The mechanisms behind the specific acupuncture effect

1.3.1. *The description of acupuncture*

An important part of the description is the ancient thoughts and history of acupuncture dealt with in previous sections. In addition acupuncture must be described by also looking at present attitudes to acupuncture and current thoughts and beliefs among patients, acupuncturists and medical doctors. High quality international studies on attitudes to acupuncture are mainly performed among doctors and are presented in table 3 (p 27).

1.3.1.1. **Research on attitudes to acupuncture in Norway**

Approximately 80 comments and letters concerning strong feelings for and against acupuncture written by Norwegian authors have been published over the last 30 years in the Journal of the Norwegian Medical Association (Tidsskr Nor Lægeforen).

In addition to these more or less emotionally motivated contributions to the acupuncture discussion, some of the first informative papers on acupuncture in Norway were presented in “Tidsskr Nor Lægeforen” in the period 1970-1990 (Bentze 1973, Kaada 1974, Heyerdahl 1986).

Only during the last five to ten years, peer-reviewed papers on Norwegian research on attitudes to acupuncture have been published. Most of these studies investigate attitudes to alternative medicine in general, which definitely complicates the interpretation of attitudes to acupuncture in particular.

In 1990, Christie presented some characteristics of persons visiting alternative practitioners. By using data from the National Health Survey of 1985, and by interviewing patients who had visited alternative practitioners, she found that patients who have seen an alternative practitioner are more likely to use a form of self-care afterwards (Christie 1990).

Professor Risberg at the Department of Oncology, University Hospital of Tromsø, has written his PhD thesis on attitudes to and experience with alternative medicine among cancer patients. In a questionnaire study among 630 cancer patients, he found that 20% had used Non-Proven Therapies (NPT), which included acupuncture. Even though users of NPT reported to have received less hope of a cure from their physicians than non-users, only 10% of the cancer patients believed that NPT would give a cure (Risberg 1997a). The 5-year observed survival rate was not influenced by the use of NPT (Risberg 1998). Use of NPT might even seem to predict a shorter survival from cancer (Risberg, 2003a), and alternative treatment is more common among mentally distressed cancer patients (Risberg, 2003b). Risberg has also surveyed oncology health professionals' knowledge and attitudes towards alternative medicine. Female physicians emphasised the importance of more information, knowledge and openness towards alternative treatments more than their male counterparts. They also believed that conventional health care could benefit from adopting principles from alternative medicine (Risberg 1999; Risberg, 2003c). Risberg also found that female physicians were more frequent users of NPT, most often acupuncture, than their male counterparts, (Risberg, 1999; Risberg, 2004a). Among those who have tried alternative medicine, a significant proportion had positive experience (Risberg, 2004b). It is interesting to see that Risberg through the years has altered the describing term for alternative medicine from non-proven therapies to unconventional therapies (in contrast to allopathic medicine).

Aasland and colleagues have in cooperation with the Norwegian Medical Association (NMA) surveyed knowledge, attitudes and experiences to alternative medicine in a random sample of 1272 Norwegian physicians. The results indicated poor knowledge about alternative medicine. On the other hand, four out of five physicians felt that they needed such knowledge to enable them to inform their patients. Nine per cent of the physicians had undergone acupuncture for own disease, 4% practised this method themselves, and 65% referred their patients to acupuncture. Aasland and colleagues conclude that poor knowledge and limited experience put Norwegian physicians in a weak position in the debate about complementary methods of treatment (Aasland 1997).

Another survey has explored the practice of acupuncture in Norway. A significantly higher percentage of physicians practicing acupuncture, as opposed to acupuncture practitioners with other health care education, had less than 120 hours of acupuncture training. Only a few physicians had more than ten acupuncture consultations a week. Physicians performed only a relatively small number of various acupuncture methods. Sixty-seven percent of the physicians used one or more Chinese medical concepts associated with acupuncture. Forty-five percent stated that they found non-scientific explanations for how acupuncture works reliable (Sagli, 1998). This study served as fieldwork for Sagli when she made her dissertation for the degree of Doctor Artium of University of Oslo entitled; "Acupuncture recontextualized: The reception of Chinese medical concepts among practitioners of

acupuncture in Norway”. The doctorate draw attention to what could be regarded as present sociocultural knowledge of acupuncture in the health care system in Norway (Sagli, 2003).

A recent questionnaire survey describes the use of acupuncture among Norwegian general practitioners trained in acupuncture. Fifty-two percent stated that acupuncture was the preferred treatment in more than five percent of their patients, and 70-80% used acupuncture as a supplement to conventional treatment. Acupuncture was commonly used for muscular-skeletal pain, migraine and headache. Improvement was reported in approximately three out of four patients. A low response rate of 53% limits the generalizability of the results. The interpretation of the study was that many general practitioners trained in acupuncture use the method as an integrated part of their clinical practice (Aanjasen, 2002).

An overview of the use of alternative medicine in Norwegian hospitals is presented in a survey based on information from the medical directors of the hospitals and the contacts they cited. Alternative medicine was reported by 27% of the hospitals, 19 among these used acupuncture. The most commonly cited reason for offering alternative medicine was a hospital staff member’s personal interest in the field. Alternative medicine use in Norwegian hospitals has shown a substantial increase during the 1990s (Salomonsen, 2003).

The first ever peer-reviewed study focusing *directly on* attitudes to acupuncture was the present author’s questionnaire survey among medical students in Tromsø in 1992. The results were published in the journal of the NMA in Norwegian only, and are not among the papers in the present thesis. Sixty-three percent of the students would recommend acupuncture when the diagnosis was migraine, while 14% would support a patient who tried acupuncture as cancer therapy. Eighty-six percent of the students thought that placebo could account for 25-50% of the effect of acupuncture. Most of the students wanted more scientific documentation, although 75% said that acupuncture already was, or at least should be, part of the ordinary health care system. A majority of the students wanted to learn the method, and would recommend acupuncture for their future patients (Norheim, 1993).

A follow up study among medical students in Tromsø, using the same questionnaire, was performed in 1996 and the results are presented in this present thesis (paper II). Another third similar questionnaire among medical students in Tromsø was performed in the year 2000, eight years after the first study. These results are not published in any peer reviewed journal, but are available in a report at the Medical faculty at the University of Tromsø (Nguyen, 2003). Medical students in Tromsø still have generally positive attitudes to acupuncture, younger generally more positive than older students, and female more than their male counterparts. Attitudes seem to change in a more negative direction as students achieve more medical knowledge as previously outlined (paper II). All in all, medical students in year 2000 are generally more negative to acupuncture than in 1996. However, a larger proportion indicates that they want to learn the method for use in their future practice as doctors. In 2000, students also say that acupuncture should be rejected until scientific evidence is available more often than four years earlier

1.3.1.2. International research on attitudes to acupuncture

Widespread search in Medline, Embase and Cochrane databases result in only a handful papers (Sagli 1998, Gould, 2001; Aanjesen 2002; Lipman, 2003) focusing directly on attitudes to acupuncture from any other authors than the author of the present doctorate. The

majority of the papers focus on medical students' and doctors' attitudes to acupuncture as part of alternative medicine in general (table 3).

Methodological shortcomings, however, lead to a limited number of relevant papers. Studies among less than 100 persons yield too small samples to give reliable data (Reilly, 1983; Schacter, 1993; Himmel, 1993; Zubeck, 1994; Sarel 1998; Ko, 2000; Perry, 2000; Lipman, 2003). Response rate lower than 60% can make it difficult to interpret the results (King, 1990; Verhoef, 1995b; Himmel, 1993; Borkan, 1994; White, 1997; Sikand, 1998; Lewith, 2001; Anjansen, 2002; Emslie, 2002). Some studies also suffer from a highly regional/ethical/occupational specificity rather than random samples (Anderson, 1987; Andritzky, 1995; Berman, 1995; Wearn, 1998). And finally, many papers do not make any difference between acupuncture and other complementary and alternative therapies surveyed (Wharton, 1986; Goldstein, 1988; King, 1992; Borkan, 1994; Berman, 1995; Astin, 1998b; Wearn, 1998; McPartland, 1999; Yardley, 1999).

Table 3. High quality international research on attitudes to acupuncture.

Author and year	(n)	Survey
<i>Anderson, 1987</i>	222	General practitioners and alternative medicine
<i>Hadley, 1988</i>	173	Complementary medicine and the general practitioner: a survey of general practitioners in the Wellington area
<i>Knipschild, 1990</i>	293	Belief in efficacy of alternative medicine among general practitioners in the Netherlands
<i>Lynoe, 1992</i>	330	Physicians and alternative medicine: an investigation of attitudes and practice
<i>Visser, 1990</i>	360	Alternative medicine and general practitioners in the Netherlands: Towards acceptance and integration
<i>Perkin, 1994</i>	168	Comparison of attitudes shown by general practitioners, hospital doctors and medical students towards alternative medicine
<i>Goldszmidt, 1995</i>	146	Complementary health care services- a survey of general practitioners' view
<i>Hopper, 1998</i>	800	Complementary therapies and the medical profession: a study of medical students' attitudes.
<i>Sagli, 1998</i>	298	Medical doctors and other practitioners of acupuncture in Norway: training, theoretical orientation and practice
<i>Risberg, 1999</i>	386	Opinions on and use of alternative medicine among physicians, nurses and clerks in Northern Norway
<i>Hall, 2000</i>	282	Complementary therapies and the general practitioner.
<i>Newell, 2000</i>	161	Australian oncologists' self-reported knowledge and attitudes about non-traditional therapies used by Cancer patients
<i>Pirotta, 2000</i>	488	Complementary therapies: have they become accepted in general practice?
<i>Gould, 2001</i>	132	Patient perspectives on outcomes after treatment with acupuncture
<i>Scmidt, 2002</i>	133	Cross-cultural differences in GPs' attitudes towards complementary and alternative medicine: a survey comparing regions of the UK and Germany

Among the myriads of alternative therapies investigated, acupuncture seems to be in a special position as the therapy most often tried for own disease, the therapy doctors most often are trained in, and the therapy most often referred to by physicians. The referral rate to alternative medicine in general varies between 54-93%. In most papers around 70% of the respondents in

the studies have made referrals to alternative practitioners. Among those who made the referrals, only a minor part (20-30%) paid any attention to whether the alternative therapist was medically qualified or not. In all surveys, the young, female doctors seem to have a more positive attitude to alternative medicine than their male counterparts.

Between 12-38% of the doctors practiced one or more alternative therapies. In the studies where practice of acupuncture was surveyed, between four-eight percent had experience as practicing acupuncturists. In most surveys, around 50% of the doctors stated that they wanted to learn more about alternative therapies, and that alternative medicine should be an integrated part of medical education. General practitioners' attitudes to alternative medicine were most influenced (in a positive manner) by observed benefits to their patients, or by personal or family experience of benefit. Other reasons for interest in, or referral of patients to alternative medicine was failure of conventional medicine, and patient demand.

It is important to keep in mind that the validity of the results from previous research might suffer from shortcomings when attitudes to acupuncture have been surveyed as part of attitudes to alternative medicine in general. When surveying attitudes to alternative medicine in general, acupuncture might be confused with other therapeutic methods that do not have the same position in relation to Western scientific medicine. There therefore seems to be a need for additional specific exploratory studies on attitudes to and experience with the method. The need for such data is also emphasized by the fact that an increasing number of patients seek acupuncture treatment.

1.3.2. The safety aspect in acupuncture – Research on adverse effects

Acupuncture adverse events can be classified in three main groups according to their nature: Mechanical organ injuries, infections and miscellaneous (Norheim, 1994; Norheim, 1995, Norheim, 1996a;). Adverse events could also be looked upon as more or less expected adverse reactions due to the nature of acupuncture therapy, but they could also be induced by the therapist's negligence (Yamashita, 2001).

Pneumothorax is the dominant serious mechanical organ injury, which also has been held to be the cause of death in some instances (Brettel, 1981; Carette, 1984). Cardiac tamponade has also been reported, and the causal link to acupuncture was confirmed by autopsy (Halvorsen 1995, Katoka 1997). Several mechanical injuries to the spinal cord have been caused by Japanese acupuncture techniques (Yamashita, 2001). Single cases of pseudoaneurysm (Kao, 2002), compartment syndrome (Shah, 2002), deep venous thrombophlebitis (Blanchard, 1991), nerve injury (Sobel, 1997), and urinary tract injury (Aso, 1979) have also been reported with the use of embedded needles. The Japanese acupuncture techniques "Hari" and "Okibari" may also complicate radiological/clinical evaluation and give rise to pain as hundreds of tiny needles are left subcutaneously for the rest of the patient's life (Gerard, 1993).

More than a hundred cases of acupuncture-related hepatitis-B/C/Non-A-non-B have been reported (Ernst, 2003), and HIV infection has also been linked to acupuncture in three cases (Castro, 1988; Vittecoq, 1989). Fatal staphylococcal septicaemia can also have been caused by acupuncture (Pierik, 1982), and acute bacterial endocarditis after acupuncture has been reported (Nambiar, 2001).

Allergic contact dermatitis after acupuncture has been reported. Other skin problems like argyria (Takeishi, 2002), prurigo pigmentosa (Tanii, 1991) and Bechets disease (Haile, 1997) has also been seen. Electro-acupuncture is held to have suppressed a demand cardiac pacemaker (Fujiwara, 1980). Delayed doctor-contact might also be the result if the patient visits an acupuncturist before the doctor (Norheim, 1996b). If conventional medical therapy is considered available and curative, this “adverse event” in acupuncture is serious, and might be life-threatening.

Even though the use of acupuncture has increased, there seems to be a decline in adverse events reported (Lao, 2003). Acupuncture performed by trained practitioners using clean needles is a generally safe procedure. However, failure of proper medical appraisal and errors of omission in clinical judgements by the acupuncturist can potentially lead to fatal consequences (Jobst, 1996, Norheim 1996b, Ernst 2001, Yamashita 2001).

1.3.3. Research on the acupuncture “system-effect”

Making high-quality science out of acupuncture research challenges the methodological thinking for many acupuncture researchers. It is, however, necessary to both study patient treatment response due to the total setting of the acupuncture therapy situation (system-effect) as such as well as the “needling” in isolation (component-effect). The therapeutic environment established by the acupuncturist may have a clinically significant effect on healing processes and therapeutic responses.

Clinical studies comparing acupuncture therapy with no treatment are definitely among those studies that look at the effect of the whole acupuncture setting more than the isolated effect of the needle as such. Both practitioners and researchers have to be aware of this difference, and often conclusions are drawn in direction of acupuncture needle-effect when rather acupuncture system-effect is monitored.

The impact of imagination, beliefs and emotions in healing processes has been recognized for a long time. It is likely that much of the relatively unspecific acupuncture system-effect could be explained in terms of placebo. However, further research seems necessary to elucidate whether placebo alone is responsible for these effects, or if other aspects of the acupuncture therapeutic setting contribute to the system-effect. It is necessary to explore further the system-effect of acupuncture as well as the more specific component-effect and the mechanisms behind a specific needle response.

1.3.3.1. Norwegian research on the acupuncture “system-effect”

At Sunnaas Rehabilitation Hospital, a randomised non-blinded study on the effect of acupuncture in the sub-acute phase after stroke has been performed. Forty-five patients were randomised to either an acupuncture treatment group or a control group receiving conventional stroke therapy with no additional intervention. The patients in the treatment group were given classic acupuncture three to four times a week for six weeks, each session lasting 20-30 minutes. Improvement in motor function was significantly greater among the acupuncture group than among the controls. Only the acupuncture group indicated a significantly improved quality of life. The results indicate that acupuncture gives an added

therapeutic benefit when given to stroke patients during their rehabilitation programme in the sub-acute phase (Sällström, 1995). The one-year follow up study showed that the difference between the two groups was maintained (Kjendahl, 1997; Kjendahl, 1998).

In another Norwegian clinical study, a physiotherapist/acupuncturist and colleagues have in a controlled trial evaluated the effect of acupuncture treatment in patellofemoral pain syndrome. Seventy-five patients were randomly assigned either to acupuncture treatment or no treatment. At 12 months there was a significantly better outcome for acupuncture patients according to the Cincinnati Knee Rating System ($p < 0.005$) that was maintained even in a worst-case calculation ($p < 0.03$). The study concludes that acupuncture might be an alternative therapy for patellofemoral pain syndrome (Jensen, 1999).

The third Norwegian study exploring the system effect compares acupuncture with antiflogistica in treatment of low back pain in general practice. The 60 consecutive back-pain patients were randomised to either acupuncture or high-dose antiflogistica for 10-14 days. There was no difference in reduction of pain or stiffness over a six-month evaluation period. However, acupuncture patients used significantly less analgesic drugs during the first week after start of treatment. Acupuncture patients also reported fewer new episodes of low back pain during 12 months of follow up. The interpretation of this study was that acupuncture seems to be effective in the treatment of acute low back pain. An interesting additional result was that adverse effects were less frequent seen in the acupuncture group compared with the group treated with antiflogistica (Kittang, 2001).

At Ullevål University hospital in Oslo a randomised, controlled study evaluated the effectiveness of acupuncture as analgesic during labour in terms of additional use of meperidine. One group of 106 women received acupuncture, another group of 92 women did not, and a second control group of another 102 women was drawn from the labour ward usual-care “patients”. Meperidine was used among 11% in the acupuncture group, while the use in the control groups were 37% and 29%, respectively ($P < 0.001$). Acupuncture during labour seems to reduce the requirement for other painkillers and patient satisfaction was reported to be high (Nesheim, 2003).

The first ever doctorate in Norway by an acupuncturist was recently achieved in Bergen. Acupuncturist, Terje Alræk has studied how acupuncture can be used in the prevention of recurrent uncomplicated lower urinary tract infection in adult women. Ninety-eight women were randomised to either Traditional Chinese Acupuncture (TCM) or to an untreated control group. The group who received acupuncture had a lower incidence rate (episodes/person-month) 0,49 compared to 0,108 in the un-treated control group, (95%CI of incidence rate ratio=0,23-0,86). The mean residual urine was reduced from 35,4 ml to 18,2 ml in the acupuncture group while there was no change in the untreated group ($p < 0,01$). The study also indicated that certain TCM-syndromes might benefit more on acupuncture treatment than other syndromes with the same Western medical diagnosis (Alræk, 2004).

1.3.3.1. International research on the acupuncture “system-effect”.

The number of clinical trials in acupuncture has increased tremendously, and most practitioners can easily get lost in the jungle of clinical trial information. Systematic reviews can help practitioners keep abreast of the medical literature by summarizing large bodies of

evidence and helping to explain differences among studies. However, the objectiveness of systematic review has been questioned (Linde, 2003b).

A comprehensive collection and an annotated bibliography have recently been published (Linde, 2001). A variety of databases including Medline, Embase, CISCOR, AMED and others have been sources for the review of the reviews. Forty-eight potentially relevant reviews were pre-selected in a screening process where 39 met the inclusion criteria. Among these systematic reviews, research questions that deal with the system effect in acupuncture have been identified. The aspect of separating system-effect from component effect is not, however, addressed by Linde et.al.

The effect of acupuncture in chronic pain has been summarized from 51 clinical trials and 2423 patients (Ezzo, 2000). The five RCT's that compare acupuncture to no treatment or waiting list had all a positive outcome. In the review these studies are found to have low quality leaving limited evidence for acupuncture being more effective than no treatment. Twelve RCTs compare either acupuncture alone or as an adjunct to standard care with conventional therapy. Due to varying methodological quality, no clear conclusion could be drawn.

A systematic review of 14 randomised controlled trials of acupuncture in neck pain includes 4 reviews that could serve as information about the system-effect in acupuncture (White, 1999). In these reviews, acupuncture was found to be superior to waiting-list control. The three studies comparing acupuncture with existing treatment (i.e. physiotherapy) shows that acupuncture is either equal or superior to the control treatment.

Further, acupuncture in back-pain has been examined with regard to system-effect (Ernst, 1998). In three studies comparing acupuncture for back pain with waiting-list controls, acupuncture was found to be significantly superior to control treatment in pain reduction. Acupuncture as an adjuvant to physiotherapy was also found to be superior to physiotherapy alone in two studies.

The system-effect of acupuncture in recurrent headache has also been investigated in a systematic review (Melchart, 1999). Seven studies look at the effect of acupuncture with prophylactic medical intervention or no intervention. Compared with beta-blockade, acupuncture seems to have an equivalent effect, but adverse reactions are more often reported among the drug group. Acupuncture seems superior to no intervention in two studies. However, the methodology is weak leaving the conclusions still uncertain.

A review of six randomised trials investigated the effect of acupuncture for temporomandibular joint dysfunction (Ernst, 1999) finds all the studies in accordance with the hypothesis that acupuncture is more effective than no treatment, and comparable with standard therapy or occlusal splint therapy. Both pain and joint function seem to respond. These studies are not designed to separate the component from the system effect that has been monitored in the trials.

Acupuncture has also been held to be effective in smoking cessation. The early results described by ter Riet et al show that acupuncture might be effective for the treatment of tobacco dependence, especially when compared with no treatment (ter Riet, 1990). A recent Cochrane review supports this line of thought (White, 2003). However, acupuncture is not found to be more effective when compared to other anti-smoking interventions.

1.3.4. The acupuncture “component effect” in therapy and clinical trials

While the “system-effect” in acupuncture includes the whole acupuncture-therapy-situation, the “component-effect” describes the specific “needling effect”. The randomised controlled trial (RCT) is the main scientific method used in studying this effect. Careful consideration, however, has to be made with regard to control therapy.

The control treatment should intend to mimic acupuncture in all but the specific needle-puncture-effect (White, 2001). The design and the way of performing the control procedure seem to determine the outcome (Sanchez Araujo, 1998). Standards for Reporting Interventions in Controlled Trials in Acupuncture (STRICTA) have been developed (MacPherson, 2002). The following section summarizes results from reviews focusing on component-effect where proper control has been administered.

1.3.4.1. Clinical research on the component-effect in acupuncture in Norway

In the Department of Preventive Medicine, University of Oslo the effect of acupuncture on smoking reduction has been investigated. Forty-six subjects were randomly assigned to a group receiving acupuncture treatment at points previously used for anti-smoking while the control group was given acupuncture treatment at points assumed to have no effect on smoking cessation. In the intervention group, daily cigarette consumption fell, the concentrations of cotinine and thiocyanate were reduced, and the desire to smoke fell significantly more than in the control group (all $p < 0.002$). This study suggests that acupuncture may help motivated smokers reduce their smoking or even quit (He, 1997). A recent updated report tells that the effect may last for at least five years (He, 2001).

“Bryggen Medisinske Senter” in Bergen, in association with the University of Bergen, has performed a three-armed, randomized, controlled, clinical trial investigating the effect of acupuncture in the prophylaxis of recurrent lower urinary tract infection (UTI). 67 adult women with a history of recurrent lower UTI were assigned to an acupuncture group, a sham-acupuncture group, and an untreated control group. Eighty-five percent were free of lower UTI during the 6-month observation period in the acupuncture group, compared with 58% in the sham group ($p < 0.05$), and 36% in the control group ($p < 0.01$). There were half as many episodes of lower UTI per person-half-year in the acupuncture group compared to the sham group, and a third as many as in the control group ($p < 0.05$). The results indicate that acupuncture can prevent this recurring infection in adult women (Aune, 1998).

The effect of acupuncture for epilepsy was examined in a randomised controlled study at the National Centre for Epilepsy among 34 patients with long-standing drug resistant epilepsy. Two Chinese professors of acupuncture gave 20 acupuncture treatments over a period of eight weeks. The patients were assigned to either classical Chinese acupuncture or sham acupuncture. An insignificant reduction in seizure frequency was found in both groups. The number of seizure-free weeks was increased in both groups, however only at a significant level in the sham group. There was no change in health related quality of life scores (QOLIE-89) in either group (Kloster, 1999; Stavem 2000).

A randomised, single-blind controlled study among 210 women compares acupuncture given by trained midwives with sham acupuncture. Women who received acupuncture report significantly lower mean pain scores and significantly less need for pharmaceutical analgesia

compared with the control group. The shorter duration of active time in labour in the acupuncture group was regarded due to less use of analgesic supplements. The results indicate that acupuncture reduces the experience of pain in labour (Skilnand, 2002).

1.3.4.2. International clinical research in the Acupuncture component effect.

Most of the studies in the recent collection of clinical reviews deal with the component-effect in acupuncture (Linde, 2001). As expected, many of the reviews focus on pain. The results among the identified studies are summarized in table 4.

Table 4. Clinical reviews in Acupuncture component-effect

Indication	Reviews/ trials (n/N)	Comment
Chronic pain	3 / 72	Available evidence is inconclusive and review methods differs considerably
Back/neck pain	6 / 11	Conclusions regarding back pain were contradictory and inconclusive in neck pain
Headache	6 / 25	Tentatively positive conclusion in the best studies, the remaining considered inconclusive
Dentistry	3 / 19	Acupuncture can alleviate dental pain and have beneficial effect in temporomandibular dysfunction
Rumatic diseases	5 / 23	Limited amount of positive evidence in fibromyalgia and osteoarthritis and inconclusive in other indications
Addiction	6 / 27	Claims that acupuncture is effective for the treatment of tobacco, alcohol and heroin addiction are not supported by sound clinical research.
Asthma	4 / 15	There are insufficient data to draw reliable conclusions about the effectiveness of acupuncture for asthma
Nausea	4 / 33	Available evidence is positive but equivocal. Most effective postoperative, and equivalent to antiemetic drugs
Tinnitus	2 / 6	No evidence from rigorous RCTs that acupuncture has specific effects in treatment of tinnitus
Weight reductions	1 / 4	Claims that acupuncture reduces weight or appetite not based on well-performed clinical trials
Stroke rehabilitation	1 / 6	Evidence for acupuncture effect in stroke rehabilitation are encouraging but not compelling

Reviews focusing on chronic pain all agreed that the available evidence is inconclusive (ter Riet, 1990; Patel, 1989; Ezzo, 2000). Conclusions regarding back pain were contradictory (Longworth, 1997; Ernst, 1998; Smith, 2000; Tulder, 2000) while the evidence regarding neck pain was considered inconclusive (White, 1999; Smith, 2000). Six reviews addressed various types of headache. The largest review focusing on migraine and tension-type headache (Melchart, 1999) drew tentatively positive conclusions. The remaining five reviews on chronic pain included fewer studies and the evidence was considered inconclusive.

A variety of rheumatic conditions have been addressed in five reviews. The limited evidence available so far suggests that acupuncture may have favourable effects in fibromyalgia (Berman, 1999). The majority of the available trials on osteoarthritis report improvement with both sham and true acupuncture but no significant differences between the two (Ernst, 1997; Ezzo, 2001). For a variety of other rheumatoid diseases the evidence was considered inconclusive (Jacobs, 1991; Lautenschläger, 1997).

In the complex issue on the effect of acupuncture in asthma, the available 15 trials are all small, and the results tend to be contradictory (ter Riet, 1989; Kleijnen, 1991; Linde, 2000). A possible bias in the two-armed studies could be introduced by the use of placebo points that may not be completely inactive (Martin, 2002).

Trials on acupuncture for nausea are unique as they focus almost completely on stimulation of acupuncture-point Pericardium 6 (Neiguan). Even though the results are most positive in the case of postoperative nausea (Vickers, 1996; Lee, 1999) and for early morning sickness in pregnancy (Aikins, 1999; Jewell, 2003), some studies suggest that stimulation of P6 is also effective in treating chemotherapy-induced nausea (Vickers, 1996). Some of the studies in these reviews focus on the effect of pressure instead of needles at the acupuncture points. The methodology in these studies varies greatly, and the randomised, double blind, placebo-controlled design is often bypassed or omitted. A contribution on whether acupressure could be an alternative for nausea is found in the present thesis (Paper III).

The efficacy of acupuncture is found to be superior to control intervention (i.e. sham acupuncture) only in very few conditions. However, low methodological quality leaves a number of unanswered questions. This should encourage more research. Larger sample sizes, optimal acupuncture technique, and both short-term and long-term follow up are needed. Randomisation and proper control groups have often been insufficient.

Standards for reporting interventions in controlled trials of acupuncture are also available (<http://www.who.int/medicines/library/trm/acupuncture/acupguidelines.shtml>; MacPherson 2002). The most important methodological challenge for future research is optimal acupuncture treatment, sham controls and blinding (White, 2001). A non-invasive placebo acupuncture procedure has been described and validated (Sherman, 2002). However, the consistency across acupuncturists regarding diagnostic details and choice of acupuncture technique has been described as poor (Hogeboom, 2001).

Additional sources of errors could be publication bias, and certain countries produce unusually high proportions of positive results (Vickers, 1998). And further, the production of systematic reviews might not be an objective source of knowledge due to highly variable methodological quality, most often due to differences in the selection process (Linde, 2003a; Linde, 2003b).

1.3.5. Research on the mechanism that contributes to the specific acupuncture effect

1.3.5.1. The relevance of acupuncture channels and points

Much effort has been put into identifying the anatomic origin for the traditional Chinese acupuncture points. Some of the points on the extremities are located according to defined

motor points, a point where the nerve enters the muscles (Funakoshi, 1980; Plummer, 1980; Monteiro-Riviere, 1981). Some acupuncture points also seem to have similarities with the trigger points located in studies of the muscular pain syndromes (Melzack, 1977), but a recent review revealed only 40% correspondence, much lower than previous research could indicate (Birch, 2003).

Even though the anatomic correlate for the acupuncture point still is uncertain, the connection to connective tissue seems likely (Langevin, 2001). Acupuncture needle manipulation gives rise to “needle grasp”, a biomechanical phenomenon characterized by an increase in force necessary to pull the needle out of the tissue, the pullout force. This effect is explained by connective tissue involvement, and post mortem tissue sections have showed 80% correspondence between the site of acupuncture points and the location of intermuscular or intramuscular connective tissue planes (Langevin, 2002a; Langevin, 2002b).

However, others claim muscle fibres to be involved in the local mechanism of acupuncture (Chu, 2000; Chu, 2002a). EMG measurements seem to indicate that the needle-induced muscle twitch in myofascial pain relief might be the major effect in acupuncture therapy for these indications (Chu, 2002b; Chu 2002c). The response to the muscle twitch is also proposed as, at least in part, the explanation for what is called *deqi*; the needle sensation (Park, 2002).

Low electrical resistance (Still, 1988), infrared radiation (Bogdanov, 1979), and increased carbon dioxide relief from certain points in the skin (Eory, 1984) have also been investigated in attempts to verify the acupuncture points. However, these theories still seem to be speculative, and the relevance of this research is questionable.

Much the same can be said about the research on meridians or channels. Theories of low resistance measured between acupuncture points on channels on the extremities have not been validated (Reichmanis, 1979). A proposed theory states that lowered the electrical resistance could be explained by gap junctions and thus imply intracellular communication according to the acupuncture channel theory. Some acupuncture points are thus described as “organizing centres” of the body (Shang, 1989).

In China much interest has been focused at the “energy–sensation (*deqi*)”, the feeling of Qi according to Traditional Chinese Medicine. The sensation of Qi has been called the propagated sensation along the channels (PSC). At the “All-China conference on acupuncture and Moxibustion and acupuncture anaesthesia” held in Beijing in 1979, previous research in this field was collected in “Research on acupuncture, Moxibustion, and acupuncture anaesthesia (Chang, 1986).

These research reports summarize the empirical viewpoint in which phenomenon of propagated sensation along the channels is described, and how the sensation along the channels can be compared to phenomena in the cerebral cortex. The *de-qi* (energy sensation) caused by needle manipulation also leaves a transient decrease in skin resistance response level (Liao, 1998). Other reports point at the limitation of propagated sensation along the channels according to level of consciousness, and how sensation along the channels can be induced or improved during hypnotic therapy.

One could hope that more recent publications could increase the knowledge in the field and broaden the understanding of the nature and location of acupuncture points and channels.

Since 1990 nearly 200 articles are published in medical journals found under the search word acupuncture and mechanisms. Among these, more than 30 are indexed as review papers. However, the major part of these indexed review papers are theoretical explanations and appear to be more beliefs and interesting thinking than unequivocal basic research.

The research on acupuncture points and channels still suffer from the fact that the nature of the acupuncture points is poorly documented. However, some interesting basic research results focus on the human neurophysiological response to needle stimulation of certain points of the body. The development of neuroimaging tools, such as positron emission tomography (PET) and functional magnetic imaging (fMRI) make non-invasive studies of acupuncture effects on the human brain activity possible.

Studies using PET indicate that thalamic asymmetry present among patients suffering from chronic pain was reduced after undergoing acupuncture therapy. fMRI has proposed relationships between particular acupoints and the visual cortex (Shen, 2001; Li, 2003). Further, needling two of the most frequently used acupuncture points (Stomach 36 and Large Intestine 4) seem to activate structures of descending antinociceptive pathways and deactivates multiple limbic and subcortical areas subserving pain association (Wu, 1999; Hui, 2000). Stimulation of cerebral cortex and the subcortical nuclei also seem to be a consequence of electroacupuncture (Liu, 1996). Acupuncture has also been claimed to stimulate gene expression on neuropeptides (Kaptchuk, 2002)

After all, it is necessary to realize that aspects of the Chinese research in the area of specific acupuncture effect are not in accordance with Western scientific standards. In many papers, especially the early ones, the places where the research was performed are not mentioned, the number of people included is not mentioned, and in some Chinese collections of research the authors' names are not mentioned. According to conventional scientific requirements, the scientific basis for the points and meridians therefore still is uncertain.

1.3.5.2. The mechanism of acupuncture therapy for pain

Acupuncture for pain relief is one of the treatment situations best investigated and explained in terms of Western medical theories. The understanding of possible mechanisms for pain control in acupuncture is based on modern theories and recent neurophysiologic research.

A new era of pain research started with the gate-control theory formulated by Melzack and Wall in 1965 (Melzack, 1965). They postulated that sensory impulses in thick myelin-coated nerve fibres influence the transmission of pain signals. Stimulation of these thick fibres seem to block the pain signals by "closing the gate" for transmission of the pain signals in the dorsal horn of the spinal cord, and in the thalamus. According to this theory, a wide range of sensory stimuli like cold, heat, massage, and also acupuncture lead to blocking of the pain signals.

After the gate control theory, the role of neurohormones has gradually been acknowledged for the last 25 years. In 1975, the first endorphins were discovered (Hughes, 1975; Terenius, 1975), and now, more than 50 different neuropeptides, monoamines, simple amino acids, and intracellular secondary messengers with influence on transmission of pain signals have been discovered. The Norwegian neurophysiologist Birger Kaada has also contributed to this research (Kaada, 1982a; Kaada, 1986; Kaada, 1989).

Acupuncture seems to enhance and facilitate production and secretion of beta-endorphin (Sjölund, 1977; Malizia, 1979; Kaada, 1982a; Pomeranz, 1989). Naloxone (an opiate antagonist) inhibits the acupuncture effect (Sjölund, 1979). Blocking the re-uptake mechanism of serotonin into the serotonergic nerve terminals increases the level of acupuncture analgesia. Conversely, injection of agents blocking the synthesis of serotonin attenuates the effect of acupuncture. (Bensoussan, 1996).

There are a number of problems with this kind of neurophysiologic research. It has largely been performed on animals, and the broad extrapolation of these results to humans may not be valid. Further, electric stimulation of the needles is often used instead of the classic manual stimulation.

1.3.2. Other mechanisms in acupuncture therapy

A number of animal-based studies have given interesting knowledge concerning the endogenous neurohumoral system in the effect of acupuncture (Sher, 1998; Irnich, 2002). A feline model indicates reversal of reflex-induced myocardial ischemia by median nerve stimulation by acupuncture (Li, 1998). In another Chinese study, the sympathetic cardiovascular reflex response induced by acupuncture was reversed by intravenous injection of naloxone (Chao, 1999).

The involvement of the autonomic nervous system is also found when acupuncture was performed in anaesthetized rats (Lin, 1998; Loazia, 2002; Murase, 2000). The inhibitory effect of acupuncture on stress responses evoked by tooth-pulp stimulation in rats has been investigated repeatedly (Han, 1999). The opioid signalling has been acknowledged as being the major explanation for the acupuncture effect (Guynet, 2002).

Acupuncture also seems to have anti-inflammatory effects (Zijlstra, 2003). The acupuncture-controlled release of neuropeptides from nerve endings and subsequent interaction with cytokines brings acupuncture beyond the endorphin concept (Bonta, 2002)

However, neurohormones have been found in many parts of the body other than the brain and nerve fibres. A paper from the National Institute of Mental Health in USA states that neurohormones might be the key to a new understanding of body and mind as an integrated whole. Their research has suggested that consciousness seems to be projected into various parts of the body, leading to the modern idea of the integral body-mind concept (Perth, 1986).

An experimental study of electroacupuncture on auditory impairment caused by kanamycin in guinea pigs also shows that effects of needling go beyond the transmitter and hormonal levels. An improvement in the cochlear function and excitability of the cortical and lower auditory centre and increased hair-cell activity may be a part of the acupuncture effect (Liu, 1999). The neuropsychological effects of stimulation of acupuncture points have also been detected through scalp-recorded potentials (P-300) evoked by auditory stimulation and the modulation of these measurements under acupuncture stimulation (Hsieh, 1998).

Acupuncture might also have the ability to enhance physiological relearning that can explain some of the “build-up” effect, resulting in lasting changes different from the pattern of illness (Bensoussan, 1996; Carlsson, 2002).

2. Aim of study

Conventional medicine is *primarily* based on evidence-based therapeutic agents and procedures. Substances and therapeutic options are identified and thoroughly developed through stringent basic research; first in laboratories, then in animals, and finally through elaborative research on humans. The therapies are then introduced on the “therapeutic market” after a gate-keeping body, for example the Food and Drug Administration in the USA when it pertains to pharmaceutical drugs, has evaluated the documentation.

For unconventional therapies, the situation can be considered somewhat opposite. Many of the therapeutic modalities within alternative medicine are already widespread as therapeutic options before research has started in the area. Unconventional therapies should therefore first be described in terms of utilisation and attitudes. As the methods are commonly used, there is also a need for analysing the safety aspect. Unconventional medicine should also be investigated as a system, before looking at the component involved and the final research approach could be research on mechanisms. Among unconventional therapies, acupuncture seems to be one of the therapeutic options most often used by the public and most commonly referred to and practiced by medical doctors.

The aim of the present study is to describe the position and role of acupuncture in terms of attitudes to and experience with the method among medical students, doctors and within the general population.

The thesis involves mainly level one in the research strategy, but the clinical trial addresses issues at level four. The summary also presents some data on level two.

The following specific research questions are covered:

- ❖ Do Norwegian doctors have experience as acupuncture patients, and what are their general attitudes to the method?
- ❖ Do attitudes to acupuncture among medical students change during medical studies?
- ❖ Does the general Norwegian population use acupuncture, and what is their experience with the method?
- ❖ Are attitudes and beliefs concerning placebo in acupuncture different among medical students, doctors, acupuncturists and the general population?
- ❖ Can acupressure alleviate nausea in early pregnancy?

3. Materials and methods in the studies

Shortcomings in methodology are often seen in alternative medicine research. Every paper in the present thesis has its own presentation of material and methods and details are therefore not included here. However, some common topics and additional considerations are important to cover.

3.1. The questionnaire studies

From February 1994 to June 1995 anonymous questionnaires were distributed among 1466 randomly selected doctors, 354 medical students, 605 acupuncturists and a random sample of 1100 persons in the general population of Norway. The response rates obtained were 77% for the doctors, 83% for the medical students, 71% for the acupuncturists and 61% in the general population. The questionnaires were returned in a pre-addressed, stamped envelope.

All questionnaires included enquiries concerning having tried and/or willingness to try acupuncture, attitudes to placebo in acupuncture, and attitudes to the use of acupuncture in migraine and cancer, representing two contrasting categories of complaints. Migraine is a painful although not life-threatening condition where acupuncture often is used. Cancer, on the other hand, is a potentially life-threatening condition in which acupuncture has little place in the cure of the disease. Those who had tried acupuncture were asked about their reasons for seeking acupuncture treatment, and their familiarity with acupuncture adverse effects.

Some minor adjustments on the wording of the questions were made according to expected knowledge and experience among the subjects. In the question of placebo a short explanation was given to the medical students, the acupuncturists, and the general population. The placebo effect was explained as “being an effect that can be attributed to faith in/confidence in acupuncture”. The question about use of acupuncture for cancer patients was addressed slightly differently to the doctors, medical students, acupuncturists and the general population. The general population sample and the acupuncturists were asked what advice the doctor should give to the cancer patient who wishes to try the method. Medical students were asked what they thought they would do as future doctors in advising a cancer patient that wishes to try acupuncture, while the doctors were asked directly what they advised a cancer patient to do.

In all the surveys a conventional significance level of 0,05 and a power of 0,80 was chosen when doing the calculation of sample sizes. The statistical analysis was done utilising the chi-square test. Adjustments were done by the Mantel-Haenschel method for stratified data. The computer software used was EPI-INFO (Dean,1990; <http://www.cdc.gov/epiinfo/epiinfo-htm>).

3.2. The clinical study on acupressure for morning sickness among 97 women

One hundred and thirty-nine pregnant women responded to the fliers at the offices of general practitioners and at pharmacies in the urban area of Tromsø. Forty-two women were

excluded due to study selection criteria, and this study thus comprises 97 pregnant women. The acupressure treatment was given by the use of a wristband with a knob on the inside. From the outside, the placebo-wristband looked identical. But on the inside the placebo-wristband had a felt patch instead of the protruding knob. The knob had a diameter of approximately 1 cm, was round in shape, and protruded about 1 cm below the inside of the wristband.

The study was carried out from January 1995 until March 1996. Every pregnant woman participated for 12 days: a four-day run-in, a four-day intervention, and a four-day follow-up period. Symptoms of nausea and vomiting were recorded daily during this 12-day period. Participants were asked to make three recordings of their problems every evening.

Outcome measurements were chosen according to previous research (Dundee, 1988; De Aloysio, 1992; Bayreuther, 1994; Belloumi, 1994). The first registration was to determine what problems they had had that particular day; 1=no problems, 2=nausea, but no vomiting, and 3=vomiting with or without nausea, regardless of how often and how many times they vomited. The women were also asked to estimate how many hours they had suffered each day. Finally, every evening the women also filled in a score of overall evaluation of their symptoms on a non-graded visual analogue scale (VAS).

In our pre-trial power calculations we chose a significance level of 0.05 and a power of 0.8. We assumed that 30 % of those wearing placebo wristbands would experience symptom alleviation and wanted to be able to detect a beneficial effect among 60% in the acupressure group. According to these calculations 100 participants should be enough to significantly demonstrate a difference of this magnitude between the use of acupressure-wristband and placebo-wristband. Power calculation was done on this categorical outcome variable only. The continuous outcome variables would have a higher statistical power. The statistical analyses were done utilising the chi-square test and t-test and two-sample t-test. The computer software used was EPI-INFO.

4. Summary of results in the papers

4.1. Doctors attitudes to acupuncture - A Norwegian study.

A random sample was drawn from members of the Norwegian Medical Association. Of the 1135 responding doctors, more than eight per cent had undergone acupuncture treatment, and 38 % of these reported benefit from the treatment.

Fifty-three percent would realistically consider acupuncture if they got problems or diseases where acupuncture treatment could be an alternative. Male senior hospital doctors were the subgroup with the lowest reported use of acupuncture, and they also showed the lowest degree of willingness to try acupuncture if they got problems or diseases where acupuncture treatment could be an alternative.

More than 38 % recommended acupuncture treatment to their migraine patients. More than four out of five doctors would not try to interfere with a patient's wish to try acupuncture treatment for cancer.

81% said that acupuncture is, or should be integrated in the national health care system. More general practitioners held this view than other doctors ($p < 0.001$). Positive attitudes were strongest among doctors who either had already undergone acupuncture treatment or intended to do so.

4.2. Changes in medical students' attitudes towards acupuncture: The possible impact of role models

All medical students in 1992 and 1996 at the University of Tromsø were invited to fill in a questionnaire monitoring attitudes to acupuncture. In 1992, 93 % in the first and second year and 64% in the fifth and sixth year responded to the questionnaire. In 1999, the corresponding response rates were 81% and 71%.

After four additional years in medical school a higher proportion of students would not consider acupuncture if they had complaints or diseases where acupuncture could be an alternative (4,0% versus 13,7%, $p = 0.03$). A higher proportion would actively advise their future migraine patients against acupuncture treatment (2% versus 13,7%, $p = 0.005$). When asked about what advice they would give to a future cancer patient, who they could not help with conventional medicine, the result is in the same direction (6,0% versus 20,5%, $p = 0.008$).

When asked about what position acupuncture should have in the health care system, a higher proportion held that acupuncture should be rejected until more scientific effect documentation was available after four additional years in medical school (8,6% versus 23,1%, $p = 0.004$). The students also lost interest in learning more about acupuncture (19,2% versus 4,1%, $p = 0.004$).

Although the proportion of students who were highly negative were in the minority in each class, the changes from the baseline to the follow-up survey were found to be significant and in a consistently negative direction. The change in attitude among medical students as they go through medical school seems not to be a cohort phenomenon. Students going through the

medical school could be influenced by the educational process to change their attitudes towards acupuncture in a negative direction.

4.3. Acupressure for morning sickness in pregnancy - A randomised, double-blind, placebo-controlled study.

In 1995-1996, pregnant women in the urban area of Tromsø municipality were invited through flyers handed out by general practitioners and pharmacies. Among the 139 responding women, 23 met the exclusion criteria, and another 19 had gone beyond 12 weeks gestational age before entry. The study thus comprises 97 pregnant women. The majority of all the women improved their symptoms of nausea and vomiting in early pregnancy using Acupressure Wrist Band (AWB) or Placebo Wrist Band (PWB). More women in the active group responded positively, although a significance level of five percent was found only with regard to duration of symptoms. The mean duration of symptoms (hours) had been reduced 2.74 hours and 0.85 hours, respectively ($p=0.018$). There was also a small non-significant difference with regard to overall grading of symptoms according to the VAS-scale. The analysis showed no difference between the active and the placebo group based on the participants' registration of daily symptoms on a five-degree grading scale used in previous research.

Questioning the women after the follow-up period showed that 38% of those who had worn AWB thought they had used AWB. Fifty-nine percent of those in the placebo group thought they had used PWB. There was no difference between the AWB and the PWB groups in the use of assigned wristbands after the termination of the study.

63% of participants in the active group, and 90% of the participants in the placebo group experienced problems when using the wristband ($p=0.004$). Pain, numbness, soreness and swelling of the hands were most often reported. No serious adverse effect was mentioned, but three women (two AWB and one PWB) reported increased emetic problems when using the wristband.

4.4. Acupuncture patients in Norway - Results from a questionnaire among a random sample in the general population.

A random sample was drawn from the office of the National Registrar in Norway. Among the 653 responding persons (61%), 19% had undergone acupuncture therapy for own disease, most often for muscular-skeletal pain.

Lack of effect of conventional medicine was most often given as the reason to try acupuncture. Acupuncture patients had twice as often as others tried other kinds of alternative medicine ($p<0.01$), most often homeopathy. Individuals who had tried acupuncture visit their GP more often ($p<0.01$), and are more concerned about own health ($p<0.01$) than individuals who have not tried acupuncture.

Sixty-six per cent of those having tried acupuncture reported benefit, while seven percent reported adverse effects. Fifty-six per cent indicated that doctors should recommend acupuncture for their migraine patients. Thirty-four per cent of those without acupuncture

patient experience say the same ($p<0.01$). Both patients who have tried acupuncture for own disease, and those who have not, indicate that the doctor should not interfere in the cancer patient's wish to try acupuncture.

4.5. Attitudes to placebo in acupuncture – Results from a questionnaire among doctors, medical students, acupuncturists, and the general population.

A questionnaire was sent to 1466 randomly sampled doctors, 354 medical students, 290+315 acupuncturists, and a random sample of 1100 in the general population. Response rates were 77%, 83%, 68%+74%, and 61% respectively.

Among all 2514 responding subjects, 57% indicated the treatment effect seen in acupuncture to be mainly a genuine acupuncture effect, 30% indicated that half of the effect in acupuncture can be attributed to placebo, while 13% indicated that the treatment effect in acupuncture is mainly a placebo phenomenon. Among doctors, 39% indicated the treatment effect in acupuncture to be mainly genuine, while the proportions among medical students, the general population, and the acupuncturists were 47%, 74% and 84% respectively (all $p<0.001$).

General practitioners and doctors who themselves practice acupuncture have similar attitudes as patients in the general population, but having tried acupuncture for own disease is significantly associated with a positive attitude within all study groups. Doctors/students who indicate that they would dissuade a cancer patient from trying acupuncture held placebo to be the major part of the treatment effect to a larger degree compared to doctors/students who would either recommend or act neutrally regarding acupuncture therapy for cancer patients ($p<0.001$). This difference is not found within the general population and acupuncturists.

The presentation of attitudes to placebo in table 3 in paper V compares those having tried acupuncture and those who have not within all four study-groups. This gives rise to four p-values in every group. The calculated relative risk reports the likelihood of saying placebo is of little importance ($<50\%$), given you have tried acupuncture. However, the calculation of relative risk was performed in the wrong direction in the 2x2 table. The correct RR-value is for doctors 0,95 (95%CI=0,91-0,98), medical students 0,89 (95%CI=0,81-0,97), acupuncturists 0,83 (95%CI=0,83-0,97), and in the general population 0,57 (95%CI=0,49-0,67).

5. General discussion

The general discussion about acupuncture requires a versatile approach and involves numerous topics. In an attempt to clarify and simplify present knowledge, the research in acupuncture has therefore previously in this thesis been subdivided into five different levels of knowledge; 1=description, 2=safety, 3=system efficacy, 4=component efficacy, 5=mechanisms.

Acupuncture has definitely become a treatment option when patients make their choice of therapy, despite the lack of definite scientific documentation of system or component efficacy. The present thesis addresses mainly the descriptive part in this research approach, but also includes aspects of component efficacy and touches on the safety issue.

The following section 5.1 discusses the scientific principles and challenges involved in the questionnaire research presented. The next section 5.2 deals with methodological problems in research on component efficacy. Section 5.3 discusses how the knowledge presented in this thesis contributes to knowledge in the field of attitudes to and experience with acupuncture, the safety considerations and the role of acupuncture in health care. Conclusions are presented in the final section 5.4.

5.1. The questionnaire studies

Data in the first survey on attitudes to acupuncture among medical students in Tromsø in 1993 indicated that it could be interesting to do a similar study among medical doctors. Are attitudes to acupuncture different in medical doctors?

To broaden the picture on attitudes and experience with acupuncture the same questions were addressed to the acupuncturists. Do they have the same experience, opinions and attitudes as doctors and medical students?

To further broaden the picture of attitudes to and experience with acupuncture, a questionnaire survey in the general population was also needed. The study among medical students needed to be repeated in order to explore whether the apparent shift in attitudes among medical students from the first to the last years of medical studies was a cohort phenomenon or whether attitudes to acupuncture change during medical studies.

5.1.1. The science of questionnaire studies.

During the 1940s, a number of experiments on attitude-question wording and form were carried out by academic and commercial survey researchers, seeking to determine whether different ways of asking the same attitude item led to different results. By the early 1950s, such question wording experiments had largely disappeared from major surveys. It was not until the 1970s that the research in this field again took place on a larger scale. Cognitive theories and contextual influence was during the 1970s acknowledged as more important factors when considering responses in questionnaire surveys than previously thought. More than two decades of research was then in 1996 presented in two major classical textbooks;

“Thinking about answers” (Sudman, 1996) and “Questions & answers in attitude surveys” (Schuman, 1996). These two classical works are still a major source of scientific thought in the field of questionnaire research (Personal information, Sissel Eriksen, Institute of Social Science, University of Tromsø).

When scrutinized, almost every survey question in any survey could be subject to criticism. Basically, the methodological problems in questionnaire surveys can be reformulated to comprise some broad classes of problems; open versus closed questions; the don’t know responses; middle alternative and neutral positions; balance and imbalance in question form and content; and strength of attitudes. These are the major considerations confronting any survey practitioner. In addition, other challenges to be considered are for instance the subject matter, difficulty of vocabulary, question length and wording. The first categories of methodological problems are dealt with in this section, while the latter challenges are included in the discussion in the bias considerations in chapter 5.1.2 and 5.1.3.

Not every existing closed attitude question can automatically be transformed to a parallel open form although a respondent always could be asked to discuss a general topic. Open responses, on the other hand, do not limit responders to alternatives within the investigator’s frame of reference, and avoid suggesting or imposing answers the respondents may not have considered. The open form also allows future scientists to create in retrospect new questions on the same subject. The discussion about open or closed questions is probably the most basic decision an investigator must take when planning a questionnaire survey. Important questions to be considered should be explored first by using an open issue in a sufficiently large pilot study. Most subjects to be considered could then probably, without losing focus, be successfully turned into closed questions to benefit easier and cost-effective coding and analysing.

Most survey investigators are willing to allow a don’t- know (DK) response to a research question, however often with considerable reluctance since it reduces the effective sample size and representativity for the item. While some training manuals urge investigators not to accept DK too easily, others include a DK alternative as an explicit part of the question, or even precede the question with a “DK filter” that asks whether the issue is one on which the respondent has an opinion or not. A “DK filter” usually affects about a fifth of the respondents, for most items. Persons who give a substantive response to an item in standard form and a DK response to a filtered version of the same item are categorized as “floaters”. There seems to be little effect of floating on relations between attitudes and most background factors, and floating is not often an important source of instability in attitude marginal.

In many cases, a question has a logical “middle alternative” (MA). Some investigators prefer to omit the MA “about right” on the grounds that almost everyone really leans in one direction or the other on most issues, and that MA invites evasion. In most issues between 10-20% tend to choose the MA when this option is offered in a forced choice attitude item. Most background characteristics, as for instance educational level, are generally unrelated to the form effect of MA. The phenomenon of choosing the MA is, however, more frequent among respondents reporting low intensity of feeling on an issue compared to among those reporting high intensity. When constructing a questionnaire it is of some importance to separate logical position from ordinal position in surveys.

Some questions can be considered unbalanced because they state only the affirmative side of the issue, and “fairness” in questionnaire studies often require the addition of a

counterbalancing argument. Persons with a lower educational level and/or no strong feelings on an issue seem to be more susceptible to arguments and counterarguments built into the wording of the question. Some researchers also believe that almost all unbalanced or even formally balanced questions are susceptible to an acquiescence bias, so that there is some general tendency toward agreement apart from content. Others held that people in general are mainly influenced by content of words and arguments rather than “mechanical sets” such as acquiescence. The agree-disagree statements provide a special case of unbalanced question forms. Wherever possible, there are methodological reasons to choose forced-choice versions of items over agree-disagree versions.

Simple pro and con position tells us only a limited amount about attitudes, and one useful supplement is a measure of the strength or indeed passion with which attitudes are held. Intensity measurements are contextually dependent, and therefore open to influence from other features of a survey and other characteristics of the people who report them. The addition of attitude strength measurements to an attitude survey can in this manner deepen our understanding both substantively and methodologically of public values and of the public’s responses to the issue. Reliable attitudes that exist independently of measurement and methodology are a matter of attitude crystallization, and are reflected in self-reports of attitude strength in terms of intensity and centrality.

The purpose of this section was to summarize a small part of the knowledge with regard to questionnaire surveys. It is, however, difficult to identify specific recommendations due to tremendous complexity, both cognitive and social, that constitute the survey situation. For the research in the present thesis, careful consideration has been taken by implementing the available principles for questionnaire surveys. Trying to explore the scientific thoughts of social science was part of the strategy in producing a questionnaire that could obtain valid and reliable information about the respondent’s attitudes and beliefs.

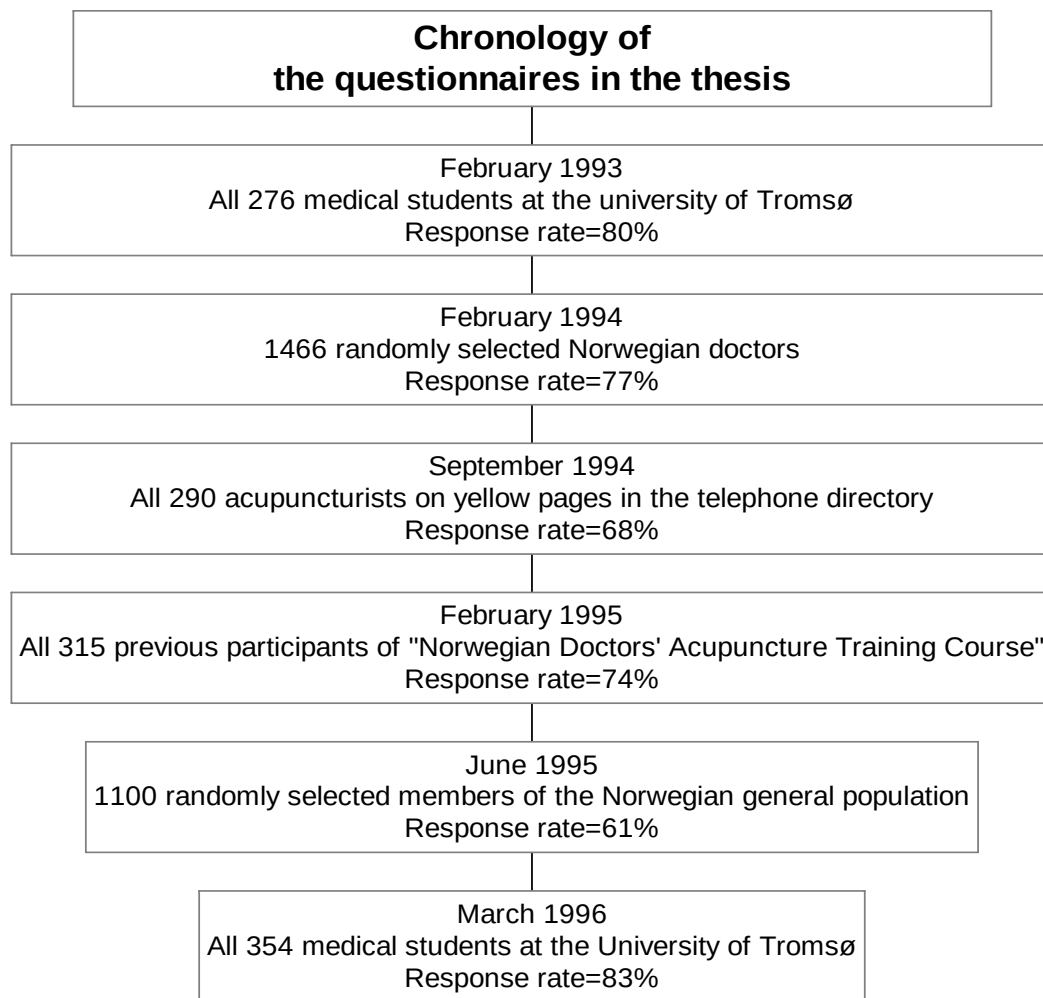
5.1.2. Methodology in the questionnaire studies.

Data for the papers in the present thesis are obtained over a period of 3 years between 1993 and 1996 (figure 6, p 47).

In the planning process, it was challenging to find the appropriate question to address groups with widely different medical backgrounds. The common thread through all the surveys has, however, been to collect data that made it possible to compare attitudes to and experience with acupuncture between the doctors, medical students, patients and acupuncturists.

In an attempt to avoid loss of internal validity, some of the commonly asked questions were modified and thus tailored to the different groups’ medical background. This modification and tailoring was especially challenging with regard to contribution of placebo to the clinical effect of acupuncture. Placebo was described more than 50 years ago (Pepper, 1945), and an important article concerning placebo was “The powerful placebo” by Henry K Beecher (Beecher, 1955). He was probably the first author to quantify the effect of placebo in a variety of diseases. He claimed that the symptoms of 35% of approximately 1000 patients in 15 studies were satisfactorily relieved by placebo alone.

Figure 6. Chronology of the questionnaires.



The placebo effect has ever since been regarded to be active in almost every disease, and estimates of the extent of the placebo effect have gone far beyond Beecher's 35 % (Roberts, 1993; Turner, 1994). However, objections to the supposed activity of placebo have been made, and some state that the significance of placebo is *not* based on critical data-orientated review of literature (de Oliveira, 1995; Kienle, 1997). Although placebos had no significant effects on objective or binary outcomes, they had possible small benefits in studies with continuous subjective outcomes and for the treatment of pain. Outside the setting of clinical trials, there is no justification for the use of placebos. It has even been claimed that little evidence is found for a powerful clinical effect of placebo, although small benefits is recognized in studies with continuous subjective outcomes and for the treatment of pain (Hrobjartsson, 2001). The placebo effect has also been called the dark side of the Randomised Controlled Trial's (Kaptchuk, 1998).

Keeping this major disagreement in mind, it is difficult to draw a crystal clear definition of placebo and the magnitude of this effect. In the reference database "Medline" the placebo effect is defined as "an effect usually, but not necessarily, beneficial that is attributable to an expectation that the regimen will have an effect, i.e. the effect is due to the power of

suggestion” or “an improvement in the condition of a patient that occurs in response to treatment but cannot be considered due to the specific treatment used” (<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>).

For the survey of the doctors in the thesis, the placebo-concept was not explained. A short explanation was, however, given to the medical students, acupuncturists, and the general population. Placebo was explained as “being an effect that can be attributed to faith/confidence in acupuncture”.

The respondents in all four surveys were asked how much of the healing effect in back pain therapy could be attributed to the placebo effect. The given five response categories were: 0, 25, 50, 75 and 100%. In most analyses 0 and 25% were grouped into one category (<50%), the same was done when the response was 75 and 100% (>50%). In paper IV, 50%, 75% and 100% were recoded into a combined category of 50% or more. It can be argued that different views are combined that could mask important nuances in the response patterns. However, these adjustments of responses are described in the paper.

To measure referral and recommendation of patients to acupuncture therapy, two totally different disorders were given as examples. In the question of referral of migraine patients, the question is pinpointing deliberate recommendation of acupuncture. The doctor is described as partaking the initiative in “putting the topic on the table”. In the case of cancer, the patient is described as the initiator. He/she asks the doctor for advice concerning the use of acupuncture. Asking for use of acupuncture for a specific disease as for instance cancer might tempt the respondents to give emotionally influenced responses about attitudes to acupuncture in migraine and cancer treatment.

In these questions minor changes had to be made to cope with the different perspective and medical background of the respondents. In the case of migraine, the doctors were asked what advice they would give their patients, while the students were asked what advice they thought they would give their future patients. The general population was, on the other hand, asked what advice they wanted the doctor to give to their patients.

The acupuncturists were not asked about the doctor’s advice, but if they ever had had migraine patients referred from doctors and if so, how often. This gives another perspective to the question of referral of migraine patients to acupuncture. As a consequence, comparable analyses on this topic were not possible to perform, and the topic was therefore omitted from the analysis among all study groups in the paper comparing attitudes to placebo in acupuncture (paper V).

In the question of advice to cancer patients, the same adaptation was made. The doctors were asked about their attitudes if the patient wanted to try acupuncture. With minor change the same wording was used for the students. The general population was asked what advice they wanted the doctor to give. The acupuncturists, on the other hand, were asked what advice they would give if the patient visited them in their acupuncture practice and asked for acupuncture therapy. Again, these minor adjustments were made according to the medical background of the potential respondents.

All the mentioned changes in wording challenge the content validity and could possibly introduce bias when comparing the responses. However, asking identical questions to doctors,

medical students, acupuncturists and the population would certainly lead to biased conclusions.

Among the medical students possible information bias would have been reduced if each student's response could be linked for those participating both in 1992 and 1996. However, when the questionnaires in the first survey were returned anonymously, it was not possible to link the two responses. Linking would have made it possible to use paired analysis of the data. This statistical method would increase the statistical power of the study that is especially important in small-scale studies. Identical results will in an unpaired analysis yield a higher p-value than paired analysis.

5.1.3. Selection bias in the questionnaire studies

The selection of potential participants in this type of studies can possibly introduce bias challenging the interpretation of the collected data and the generalizability of the results and conclusions. Selection bias can either arise due to choice of samples not representing the sampling frame. On the other hand, selection bias can also be the result if the response rate is low leading to a misrepresentation of the samples to be investigated.

5.1.3.1. Selection bias in the sampling process

Biased samples might easily arise if the sampling frame is either skewed or improper for the research question. In the survey among medical students, the whole population of medical students at the University of Tromsø received the questionnaire, which excludes any sampling bias. Students at the University of Tromsø might, however, be different from students at the other universities in Norway leading to limitations in the ability to generalize the results to all Norwegian medical students.

In the study among doctors, the sample was drawn randomly from the membership files of the Norwegian Medical Association (NMA). These membership files do not fully represent the potential optimal sampling frame of all Norwegian doctors. The difference will, however, be minor since more than 95% of Norwegian doctors hold membership in the NMA.

There is no register of all acupuncturists in Norway. The sample included in the present study consists of acupuncturists listed in the yellow pages of the telephone directory and all acupuncturists trained at the Norwegian Doctors' Acupuncture Training Courses (NDATC). The combination of these two selected groups of acupuncturists could be regarded as representative of the ideal sampling frame of all Norwegian acupuncturists. However, there still are some additional acupuncturists not found within these two groups. These acupuncturists are probably few, and the selected group of acupuncturists was considered to be the best obtainable population of Norwegian acupuncturists at the time of the survey. No further sampling was done in this group.

In the general population, the file of the National Registrar was used as the sampling frame. As the sampling frame comprises all eligible persons in the population, this basis for the sampling process should practically eliminate the possibility of this type of selection bias.

5.1.3.1. Selection bias arising as a consequence of response patterns

As dealt with in section 1.3.1.2, a low response rate makes it difficult to make general conclusions. However, a response rate above 70% will usually be enough in large population studies (Goudy, 1976). All the samples in the present questionnaires can be considered large (figure 6, p 47).

As described in figure 6, response rates for the questionnaires are all adequate for further analysis, with the possible exception for the general population. A response rate of 61% might threaten generalizability and could as such contribute to over- or underreporting of use and positive attitudes to acupuncture.

The distribution of responders among doctors in Paper I was reported as a mirror of the sampling frame. Table 1 in the paper says that the responders *truly* reflect the population of Norwegian doctors, as there are no statistical significant differences on the sociodemographic variables in the responders compared to the population. The statistical analysis used was to see if the observed sample could have arisen by chance by drawing a random sample of the given size from the membership files of the NMA. A renewed consideration shows that for two of the sociodemographic variables the observed samples would not have been found within a 95% confidence interval. It is therefore incorrect to postulate that the responders truly reflect the population of Norwegian doctors. However, the observed differences are small in absolute terms, and will not seriously threaten generalization.

The high response rate achieved in paper I was also obtained in other similar surveys on similar subjects among doctors at about the same time (Pedersen, 1996; Sagli, 1998). A consistent high response rate might therefore indicate a high interest in these issues among Norwegian medical doctors.

It is impossible to know the attitudes and beliefs of non-responders. Given a sensitive topic, there could be an overestimation of the use of acupuncture if a higher proportion of positive persons are found among the responders. An attempt to describe the “worst-case-scenario” might be to say that everyone among the 39% of non-responders in the questionnaire in the general population has negative attitudes to acupuncture. This academic exercise is performed in Paper IV. It showed that the direction and significance of the results were unaltered.

The response rate in the general population was the lowest among all the questionnaire surveys included in this thesis. Similar surveys in the population on utilisation of alternative medicine when suffering from *specific* diseases and complaints, achieved higher response rates (Risberg, 1995a; Risberg, 1995b; Jensen, 1990a; Jensen, 1990b). Surveys among patients with specific diseases, probably of understandably specific personal interest for the subject, often obtain higher response rates (Howie, 1989). But on the contrary, if acupuncture was a topic with low interest, this could explain the low response rate (Riskin, 1972; Dillman, 1978; Hanita, 2000). Research has also shown that surveys performed by an unfamiliar organisation could suffer from a low response rate (Heberlein, 1978; Smith, 1985; Lydeard, 1991).

The importance of layout (Linski, 1975; Dillman, 1978; Giles, 1978; Oppenheim, 1982; McColl, 1993), language and wording of the questions (Lydeard, 1991; Pouwer, 1998; Woodward, 1988; Jack, 1998), length and content in the questionnaire (Dillman, 1978; Jack, 1998), have through all questionnaires been carefully held in mind. Questions on a given topic

were clustered, both to aid the memory, and to utilize “skip patterns” (Jenkins, 1975; Jack, 1998). A funnel approach to possible controversial issues, and the opportunity to include further information to the answer choices should make the respondent feel more comfortable in responding to the study (Del Greco, 1987a; Del Greco, 1987b; Del Greco, 1987c; Del Greco, 1987d; Zelnio, 1980).

5.1.4. Information bias in the questionnaire studies

The lack of a “gold standard” in research on attitudes and experiences in alternative medicine might be a problem in the assessment of the internal validity of the obtained results. Questionnaires used in previous surveys were considered used when planning the study (Reilly, 1983; Wharton, 1986; Hadley, 1988; Marshall, 1990). However, none were regarded suitable to collect the necessary data according to the study protocol.

However, a pilot study, based on previous research models (Reilly, 1983; Wharton, 1986; Hadley, 1988; Marshall, 1990), was performed to validate the self-composed questionnaire. Some of the questions for the questionnaires were chosen from previously used questionnaires and adapted to Norwegian conditions. Further, the questionnaires used in previous population studies in Tromsø were also used as a template when similar topics were investigated (Fylkesnes, 1991). When the questionnaire was created, ten of the oldest medical students and ten physiotherapists were used as piloting population. Interviews with the persons who had participated in the pilot study gave some guiding principles used in the evaluation of validity and internal consistency of the *final* questionnaire (Dunning, 1996).

Information bias could occur in the study among medical students, as the investigator was their fellow classmate at the time of the first questionnaire study among medical students (Norheim, 1993). The respondents could have given different answers than they would have if someone unknown had been the principal investigator. The anonymous return of the questionnaires was particularly important in this situation, and eagerness to please the researcher could have been an issue.

Individuals with experience as acupuncture patients might feel special interest when someone shows interest in their situation and their use of alternative therapies. Such strong personal involvement might influence the information given (Riskin, 1972; Krause, 1985; Lydeard, 1991; Pouwer, 1998; Jack, 1998).

It is challenging to survey an individual’s opinion about own health within a 4-degree alternative, as done in the question on general health. How to put the question could influence the results in the survey. However, the wording of this specific question is identical to the one used in the population studies in Tromsø, the Tromsø I-IV studies (Fylkesnes, 1991) where it has shown a strong predictive ability with regard to later serious disease and death.

For some of the questions, information bias could have been introduced as especially positive or negative underlying attitudes to acupuncture as such might tempt the respondents to give emotionally influenced responses. Forcing the respondents to choose between quite few alternatives might result in polarisation rather than monitoring true opinions. It is impossible to know in what direction, and to what extent these factors have contributed to information bias. However, at the end of the questionnaire the respondents were asked to give comments

to the study as such. These comments seem to be balanced which could indicate that emotional preload with possible impact on the information given might have been balanced.

The questionnaire given to the medical students contained fewer questions than the following ones, and fewer personal data were asked for. The questions were also more personal for the doctors, as they should tell about their own practice while the students only should guess what they thought they would do as educated doctors. These factors could influence the willingness to participate and affect the answering possibly creating some degree of information bias.

The overall quite surprisingly positive attitudes to the use of acupuncture for cancer have led to a closer look at the question to seek for a possible information bias. It could be argued that the question was vague and ambiguous. A major objection to the wording of the question is that it is not stated whether acupuncture should be considered curative or palliative therapy. This could imply that respondents might interpret the question differently challenging the internal validity of the research.

Some respondents have made their own answer alternative when responding to the question of cancer. Often the doctors wanted to recommend acupuncture, but only as a limited palliative therapeutic measure. This was given as an objection to the questionnaire from approximately ten percent of the respondents among the doctors, but not among the medical students, acupuncturists or the general population. Some doctors also stated that they were offended and felt annoyed by the wording of the question. Although they answered the question, some stated that there is always *something* you can do to help a cancer patient. No such comments came from the responders among acupuncturists and in the general population, and also among the medical students this point of view was rare, and no negative comments to this question were obtained. This could imply that the wording of the question is adequate for subjects with no or little medical education and background, but rather improper or misplaced in a study population of doctors. However, the wording of the questions was kept as similar as possible to obtain comparable data from the different study groups. The response pattern among doctors might represent an underestimation of positive attitudes by their feeling of being offended by the wording of the question

Respondents might also have interpreted the terms “tried acupuncture” and “benefit” from the treatment, as no guideline was given. Perhaps those who had tried acupuncture only a few times did not consider themselves as acupuncture patients. Recall bias might also be introduced if patients forget a history of acupuncture treatment. If these two possible biases had been present, the proportion of respondents found to have utilised acupuncture would be under-estimated.

Another challenge in correlating acupuncture use for own disease and attitudes might be the well-known problem of what came first; whether trying acupuncture led to positive attitudes, or initial positive attitudes led to trying acupuncture. In the surveys, the respondents were asked about lifetime experience as acupuncture patients. Undergoing acupuncture must then have happened some time before they filled in the questionnaire. This should ensure that their experience as acupuncture patients came before they were asked to state their attitudes. It is, however, in addition possible to think that those who chose to try acupuncture did so out of their previously assumed positive attitudes to the therapy. If trying acupuncture significantly changed their previous attitudes, the results in the questionnaire might be biased and difficult to interpret. At least it would in such cases be questionable to claim that attitudes to acupuncture solely are based on acupuncture patient experience. If trying acupuncture did not

change the patient's previous attitudes, the association between trying acupuncture and attitudes still might be valid. However, it is not possible to state that their attitudes came as a result of acupuncture patient experience, only to pinpoint the association or the linkage between certain attitudes and having experience as acupuncture patient.

It could also be considered questionable to cluster responses. In the case of attitudes to acupuncture's position in the health care system among the doctors, those saying acupuncture is already integrated are combined with those saying acupuncture should be integrated. It is possible to envision that a person might say that acupuncture is already integrated, but should not be integrated further or rather rejected until more scientific documentation is available. The opinion that acupuncture already is a part of the health care system might then be inappropriate to put in the same category as those stating acupuncture should be integrated, if the respondent actually holds the opposite view. However, based on all results in the collected data the likelihood of positive attitudes connected to the statement that acupuncture already is a part of the ordinary health care system is most probable.

All the discussed factors that could lead to information bias have been thoroughly considered throughout the execution of each of the surveys. Even when keeping the discussed sources of bias in mind, the present questionnaires are considered to give valid information concerning attitudes to, and experience with acupuncture. The great advantage of the questionnaires in this thesis is also the direct focus on acupuncture, and not as part of alternative medicine in general. When mixing acupuncture with other alternative treatment, more substantial sources of information bias could be introduced.

5.1.5. Confounding

The concept of possible confounding is also important in discussing the results in the questionnaire studies. This issue is especially relevant when attempting to elucidate what factors are most importantly associated with doctors' attitudes to acupuncture. There seem to be differences in attitudes to acupuncture related to position. Senior hospital doctors are more negative than general practitioners. Factors possibly confounding this association could be sex or age in that one would imagine that attitudes toward acupuncture are different between genders and different in older compared to younger doctors. In our analyses on the doctors, however, these two variables are not related to their attitudes towards acupuncture. In the studies on medical students the confounding issue is of minor importance. The main endpoint in this study is a comparison of difference within a cohort of medical students studied at two points in time four years apart.

Age and sex could also have been factors confounding the relationship between opinions about placebo effect in acupuncture and the various studied groups. The papers in the thesis show that the groups are similar in age structure with the exception of medical students. Sex and age were, however, not variables associated with placebo opinions in any of the studied subgroups.

5.1.6. *Effect modification*

Another source of analytic concern is the concept of effect modification. In the study on medical students all results are presented sex-specifically. This ensures that possible effect modification by sex is not masked in an overall presentation of results.

In the study on doctors' attitudes to acupuncture the difference in attitude pattern between general practitioners and other doctors is clearly illustrated in figure 1 and 2 in paper I demonstrating an effect modification of professional preference.

In the study of placebo opinions both subgroup results and overall results are presented. The overall presentation of results give a rough estimate of the landscape, but it would be incorrect not to disclose that there is a strong effect modification present by studied subgroups. When effect modification is present one must put more weight on the results presented specifically for each stratum of the effect-modifying variable, in this case population subgroup.

5.1.7. *Would a qualitative model have been a better choice for research on attitudes to, and experience with acupuncture?*

Quantitative research has been described as empiricism, deductive studies, or hypothesis testing. Consequently, the quantitative approach is regarded as objective and formal, and the data obtained by a quantitative method is often regarded as "the objective truth". When working with a quantitative design, attempts to measure the accuracy of the results are made by checking the reliability and validity of the measuring instruments.

Qualitative research is more difficult to define, and is sometimes described as a philosophical and political orientation to the world of knowledge (Smythe, 2000). "Qualitative research seems to be multi-method in focus, involving interpretive, naturalistic approach to its subject matter. This means that qualitative researchers study things in their natural settings, attempting to make sense, or interpret phenomena in terms of meanings people bring to them" (Cutcliffe, 2000).

While medical doctors, especially in hospital and laboratory research, commonly use quantitative methods, the qualitative approach seems to be more common in nursing science and among sociologically orientated studies. Because qualitative and quantitative methods involve differing strengths and weaknesses, they constitute complementary, and not mutually exclusive strategies for research. Qualitative research methods seem to have gained foothold in the Norwegian medical scientific environment only in the latest decades.

A "qualitative way of thinking" was interestingly the decisive factor leading the present author into research. Based on numerous case series and extensive patient interviews in previous acupuncture practice, the idea of systematic research evolved.

For the first survey among fellow medical students in 1993, the present author chose an anonymous quantitative survey rather than a qualitative approach in an attempt to achieve a more impersonal relation to the subjects in the survey. Some of the classmates and friends were thought to possibly feel an in-depth interview concerning an assumed sensitive topic unpleasant.

Other factors such as lack of time and money have also had influence on the choice of research method. Available funding and time was not sufficient to do thorough qualitative research. This perspective was an inevitable pragmatic approach towards the choice of research design.

In the present thesis, the advantage of measuring responses from a large number of individuals to a very limited set of questions, thus facilitating comparison and statistical aggregation of the data, led in a quantitative direction. For the topics covered the results thus then became fairly widely generalizable. Some of the principles of qualitative research have, however, although to a limited extent, been held in mind. The use of open-ended or semi-closed questions can be regarded as a small attempt to retain aspects of a “quasi-qualitative” approach. The first questionnaire used among medical students included only closed questions, but the respondents were also invited to make narrative comments regarding both the questions and the study as such. In the following questionnaire among doctors, open-ended questions were introduced covering acupuncture adverse effects. In the final questionnaire in the general population, almost 40% of the questions were semi-closed or open-ended. This indicates that the importance of “qualitative thinking” has been acknowledged and appreciated. The previously outlined *description-of* and *system effect* phases of research methodology in acupuncture could probably benefit substantially from the use of qualitative methodology alongside the quantitative approach.

5.2. The clinical acupuncture/acupressure study

Research in acupuncture, in general, has only to a limited extent showed that acupuncture/acupressure can be viewed as Evidence-Based Medicine (Norheim, 2000; Linde, 2001). Randomised, double blind, placebo-controlled studies are difficult to perform when testing hypotheses concerning use of manipulative procedures (Shapiro, 1983; Rotham, 1986), even though a placebo needle has been developed (Streitberger, 2000).

Investigating acupressure (=pressure to an acupuncture point) seems to result in fewer problems in design and methodology than in research introducing the needling procedure. However, introducing a self-administered therapy gives rise to other methodological problems and other sources of possible bias.

To run a clinical study involves challenges that are different from those encountered in studies with a questionnaire design. Therefore, the study on acupressure for morning sickness in early pregnancy is in the present general discussion addressed separately

5.2.1. Methodology

The study presented in paper III is based on a principle claiming that pressure to an acupuncture point can be regarded as an alternative form of acupuncture. The point most often used for nausea treatment is point six on the pericardium channel according to Traditional Chinese Medicine. The point is located on the forearm, approximately two inches proximal to the distal wrist crease (figure 7). This point can either be stimulated by finger massage, a blunted stick, or as in the study presented in paper III a specific wristband (figure 8, p 57).

Figure 7. “Neiguan” (=pericardium 6) is the most commonly used acupuncture point in treatment of nausea.



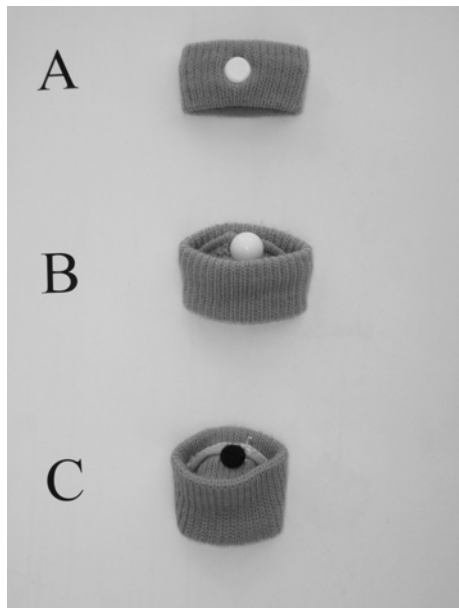


Figure 8. The acupressure wristband and the placebo wristband used in the study of acupressure in morning sickness.

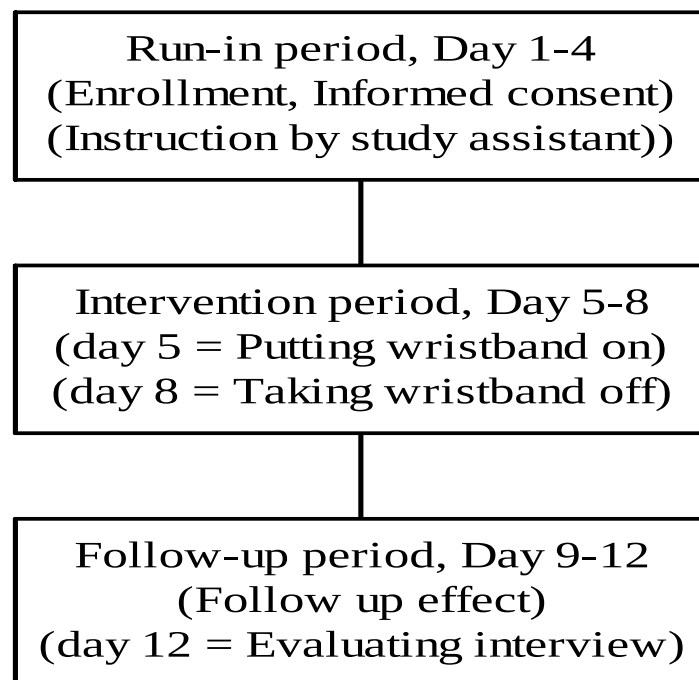
A = The acupressure wristband from the outside

B = The acupressure wristband with the plastic notch on the inside

C = The placebo wristband with the felt patch on the inside

Data for the acupressure study was obtained over a period of 15 months from January 1995 through March 1996. Each woman participated for a 12-day period according to the description given in figure 9.

Figure 9. The course of the acupressure study



Type of problem was differentiated in three categories; 1=no problems, 2=nausea, but no vomiting, and 3=vomiting with or without nausea, regardless of how often and how many times they vomited. The reported problems were then recoded to a five-degree variable. This classification was done identical to the first research on acupressure for nausea (Dundee, 1988) and has been validated through repetitive use in later trials. Based on the daily

recording there was an outcome value for the run-in, intervention and follow up period between 1-5:

- 1 = no problems (neither nausea nor vomiting any of the days within a period),
- 2 = slight (nausea without vomiting in one or more days within the period),
- 3 = moderate (daily nausea without vomiting in the registration period)
- 4 = troublesome (vomiting one or more days within a period)
- 5 = Severe (vomiting daily in the registration period)

The duration of symptoms was recorded every evening counting number of hours with complaints. The intensity was recorded on a zero-five Visual Analogue scale with zero indicating no problems and five indicating the worst thinkable level of nausea and vomiting. Duration and intensity are in paper III analysed as continuous data. Although duration often was reported in hourly or half-hourly intervals, the variable is most appropriately classified as a continuous variable.

In paper V, figure 1 and 2 present duration and intensity of symptoms on a scale that on its y-axis does not include zero for duration and one for intensity. If the reader is unaware of this, temporal differences can seem larger than if the zero or one point was included. In hindsight this point should have been highlighted either by clearly breaking the y-axis or by description in the text.

A request was made to pharmacies, doctors, and midwives practicing in the urban area of Tromsø, and the obstetrical out-patient-unit at Tromsø University Hospital to check if their pregnant women from the Tromsø municipality had ever been talking to them about the acupuncture wristband. As no one had heard about the wristband, one could conclude that the appearance of the active wristband was unknown. It is therefore safe to conclude that the patients at the start of the study were blinded to which wristband was active or placebo. The fact that the use of wristband for nausea was an unknown therapeutic measure in the Tromsø area was also the main reason for not performing a pilot study to test the protocol feasibility. If piloting the study brought to light the design of the intervention, this could contaminate the blinding and the validity, and by that the results obtained (Shapiro, 1983).

To get an equal number of subjects enrolled in the two groups throughout the recruitment period, a block randomisation design was used rather than a simple random assignment scheme. Each block of 20 subjects enrolled were randomly assigned to either Acupressure-Wrist-Band or Placebo-Wrist-Band. Ten of each of the two types of wristband were put in identical envelopes in a random order, only known by a secretary at the Institute of community medicine. It was not possible to recognize what wristband the envelope contained from the outside. After inclusion, the subject received the next envelope in the row.

The women in the study were asked in the ending interview one week after the study what type of wristband they thought they had used. A higher, although insignificant, proportion of women in the control group made a correct guess about what type of wristband they had used compared to women in the active group (59% versus 38%). This could be caused by a blinding failure, but it might be just as likely to believe that you might have been assigned to the placebo group as long as you do not improve from the intervention. Subgroup analysis of effect among those women who made correct guess was difficult to perform due to small numbers. Comparing the women who made correct guess of what wristband they had used with those who made a wrong guess and/or stated they did not know what wristband they had

used, did not result in any statistical significant difference between these two groups of pregnant women.

When asked about adverse effects, 88% among those who in the follow-up interview thought they had used active band had experienced adverse effects. The proportion among those who thought they wore placebo wristband was 75%. In the group who did not know what wristband they had used, the proportion was 77% ($p=0,60$). Beliefs with regard to active or placebo allocation do not seem to influence the experience of adverse events. However, the experience of adverse events was more pronounced in the actual placebo group as 63% of participants in the active group, and 90% of the participants in the placebo group reported adverse effect ($p=0,004$).

Could a different placebo-therapy or study design have been chosen? Looking at the results, especially figure 1 and 2, one could think that both the active and placebo group have received an active treatment. Even a wristband without the knob could theoretically give some degree of pressure to the specified acupuncture point. Nausea and vomiting generally subside with time in early pregnancy, so the reduction in symptoms over the duration of the study could have been a normal trend. To shed light on this aspect, there could have been a third control group without any intervention. This would, however, have required a higher number of pregnant women enrolled in the study. Another methodological approach in this study could have been to utilize other parts of the body in the placebo group, with or without point stimulation. Whether this would have given a better answer to the research question being addressed is impossible to say.

Dropout and subgroup analysis in this study was impossible to perform due to insufficient sample size for this analysis. In the cases where data were missing, the latest recording was used for the rest of the days in the registration period. All calculations in the study are thus based upon the returned every-day recordings from the pregnant women. This was done to ensure analysis according to the intention-to-treat principle, and should have minimized a withdrawal bias in the study. Those who dropped out from the registration were more frequently found in the placebo group, however not at a significant level. And further, those who dropped out from the study did not report adverse effects more often than the others, their last reported value did not differ from those who stayed within the trial, and there were no other differences found in the data.

5.2.2. Selection bias

Among the 139 women who wanted to participate, no further selection was made except for those 42 excluded before randomisation due to the given exclusion criteria or inability to ensure compliance with the outlined study-protocol.

The major part of the women in the study made an application in person, and a study based on voluntary enrolment can suffer from self-selection bias (Rothman, 1986). Those enrolled in the study are not representative for all pregnant women. Their attitudes and experience might make them prone to politeness and the “eager to please” response. Some women might consider nausea and vomiting as a normal part of pregnancy. As a consequence, the women who entered the study could be those who suffer most from morning sickness.

The above-mentioned factors could have caused a selection bias. This would, however, only limit the external validity, or the generalizability, of the results, and not alter the efficacy conclusion of the study.

5.2.3. *Information bias*

Obtaining information in a study always leaves a possibility for information bias, especially if it results in misclassification of subjects with regard to outcome and/or exposure (Rothman, 1986). One possible misclassification could have occurred if the women randomised to active treatment did not perform the acupressure properly, and therefore should have been classified in the placebo group. If these subjects belonging to the active group are performing placebo treatment, their results could dilute the apparent effect of acupressure in the active group.

On the other hand, the placebo effect could be due to a specific effect from the placebo treatment chosen in our study. It is conceivable that the placebo device conveyed some specific acupressure effect. If this has happened, some of the subjects in the placebo group should have been classified as receiving active intervention. This would also contribute to an underestimation of the results in the study.

Self-report measures are not always trustworthy, especially not in terms of health-related information and patient utility (Paganini-Hill, 1982; Hanita, 2000). Recall bias could appear since recording of symptoms in the evening depended on the ability to memorize the happenings during the day. It can therefore be argued that the recording of symptoms should have been done more than once during every 24 hour-period. This could give more accurate data, and the fluctuations of complaints during the day could be monitored. On the other hand, there would possibly be a compliance problem, and it is likely that the number of dropouts would increase. The nightly registration of symptoms could have contributed to the fact that only 13 women did not fill in the daily recording of symptoms throughout the 12-day trial period.

Another challenge for the women in the study was to record symptoms on the day of therapy change. The induction period may also differ from woman to woman, and the time of day when to put on or take off the wristbands was not necessarily the same for all participating women. To avoid these difficulties, the starting day and day of change (day1, day5 and day9) within each period was omitted from the analyses, and the mean of the other days in each period was analysed.

The duration of each registration period in the study might be considered too short. A longer induction time could be necessary for the therapy to give an effect, or perhaps a longer follow-up period could be necessary to record any relapse after the wristband had been removed. On the other hand, making the registration period longer could increase the possibility for spontaneous remission as the women then would increase their gestational age. According to acupuncture/acupressure theory the effect of point stimulation in nausea is immediate. Fewer days in each registration period would, on the other hand, probably result in a sub-optimal number of registration instances.

Information bias might have occurred in terms of misclassification and/or recall. It is however unlikely according to acupuncture theories that the placebo device should have a specific acupressure effect, and *if* this has happened, it would even underestimate the results in the

study because of non-differential misclassification. Recall problems might have been more likely, but the randomisation process should ensure that this source of error is equally distributed in the study groups. The effect of this potential bias would then only dilute the obtained results, not alter the conclusions in the study. Recall bias affected by the treatment result could, however, theoretically result in a misrepresentation of the result.

5.2.4. Confounding

The concept of confounding is central in modern epidemiology (Shapiro, 1983; Rothman, 1986; Sackett, 1996a). A confounder in our study must have influenced nausea in early pregnancy, and this potential factor must also have been related to the exposure given to the two study groups. Random allocation should prevent confounding in clinical trials. A successful randomisation should disperse known and unknown possible confounding variables evenly in the two groups in the study, and should therefore not complicate the analysis.

Twenty-five per cent of women in the active group indicated that they were smokers at the time of conception, while 58% were smokers in the placebo group. This could be a potential confounder given that this smoking pattern was present also under the study period. In the period from conception to enrolment into the study, a higher proportion in the placebo group quit smoking, leaving more similar proportions of smokers among women in the active and the placebo groups at the start of the study, 13% and 22% respectively. If, however, the data are analysed excluding all smokers the results and final conclusions in the study are unaltered. The difference in smoking status, therefore, seems to be an unlucky result despite the randomised study design that normally ensures the comparability of the results obtained.

5.3. The role of acupuncture in health care

Trends in the general use of alternative medicine in the United States show that 42% of Americans have used alternative medicine during 1997 (Eisenberg, 1998), a sizeable increase from 34% in 1990 (Eisenberg, 1993). Total yearly out-of pocket payment for alternative medicine professional service had also increased to 27 billions US\$ in 1997, similar to total out-of pocket payment for *all* US physician services.

National surveys in other parts of the industrial world suggest that the same tendency can be found worldwide (Goldbeck-Woods, 1996). Acupuncture is one of the alternative therapies most often used by the public (White, 1997; Ernst, 1996b; Ernst, 1997; Paper V; Perry, 2000), and is also the alternative therapy in which doctors, especially GP's, are familiar with (White, 1997; Astin, 1998a; Paper II; Pirotta, 2000; Perry, 2000; Lewith, 2001). An increasing proportion of doctors refer their patients to acupuncture treatment (Borkan, 1994; Ko, 2000; Pirotta, 2000), and a mean worldwide proportion of 15% among physicians practice the method (Astin, 1998b).

The position of acupuncture and the common use of the method indicate that acupuncture is regarded as a substantial part of the present total health care system. Contrary to conventional medicine, the use of acupuncture does not seem to need support from scientific evidence to get acceptance from patients or doctors.

As outlined earlier in section 1.3, the basic knowledge about the acupuncture mechanisms that contribute to the acupuncture effect is still unknown. Research on "component efficacy" and "system efficacy" has started to emerge, but still acupuncture cannot be considered evidence-based medicine.

The high public interest in acupuncture demands that the medical community is familiar with both the current status of acupuncture as a healing profession, how acupuncture is regarded among therapists and patients, and be aware of possible future trends. Such familiarisation should also be based on scientific knowledge in terms of attitudes to and experience with acupuncture, and a focus on the safety aspect in acupuncture therapy.

5.3.1. Attitudes to and experience with acupuncture

5.3.1.1. Importance of the knowledge in the present thesis

Knowledge about attitudes to and experience with acupuncture has, with few exceptions (Sagli, 1998; Gould, 2001; Aanjesen, 2002; Lipman, 2003), *only* been surveyed as part of alternative medicine *in general*. This limits the comparability of results in the present thesis with previous studies where alternative medicine represents a heterogeneous group of therapeutic approaches with no common body of knowledge (Gevitz, 1995). Alternative medicine is most often defined as "medical interventions that are not taught extensively in medical schools, or generally provided in the conventional health care system" (Eisenberg, 1993). The importance of separating acupuncture from other alternative therapies was one of the major reasons for the present author's very first survey on medical students' attitudes to acupuncture (Norheim, 1993). Other researchers have supported this point of view in recent

years. (Eisenberg, 1997; Dalen, 1998; Davidoff, 1998; Kaptchuk, 1998a; Ernst, 1996b; Ernst, 2000).

The term alternative medicine is both vague and insufficient, especially when comparing results from different parts of the world. Herbal medicine and homeopathy are more popular than acupuncture among patients in central parts of Europe (Visser, 1990; Himmel, 1993; Fisher, 1994), while relaxation techniques and chiropractic are the therapies most often used by consumers in the United States (Eisenberg, 1993; Astin, 1998a). There is reason to believe that attitudes to alternative medicine might vary dependant on the dominant modality of therapy people associate with the term alternative medicine.

The nature of acupuncture therapy, the partly neurophysiological explained mode of action, and the clinical research results bring acupuncture to a special position among other alternative therapies (Astin, 1998b; Pirotta, 2000; Furnham, 2000; Greenfield, 2000; Perry, 2000). This could explain why acupuncture is relatively popular among doctors.

The practice of acupuncture is still mostly based on tradition, cultural norm, regional economics, specialty of the practitioners, and their personal interest rather than evidence based outcome of treatment (Pelletier, 1997; Wennberg, 1996). Attitudes and experience with acupuncture differ between countries, and results obtained in the United States, Germany or the Netherlands might be invalid for health policy and decision making in Norway. There might even be a need for surveys within different regions of Norway as traditions in Sami folk-medicine in the far north might be very different from sociocultural bound health perspectives in the capital area.

While several other researchers present data from small, non- random samples, the present thesis does not seem to suffer from this possible bias. Further, response rates under 60%, that limit the generalizability of the results, are often seen in previous surveys. And finally, only a few studies compare attitudes between doctors and other groups. No previous study has provided contemporary and comparable data from doctors, patients and acupuncturists.

The results in this thesis have contributed to increased knowledge about attitudes to, and experience with acupuncture. Attitudes seem to be changing, and these changes should be monitored in regular surveys. It would also be of interest to explore the reasons for specific attitudes, and investigate more thoroughly the patients' motivating forces in choosing acupuncture. For this purpose, the qualitative research methodology should be considered alongside quantitative survey design.

5.3.1.2. The association between attitudes to acupuncture and acupuncture patient experience

Despite the discussion about what came first, there seems to be a linkage between having tried/willingness to try acupuncture and attitudes to acupuncture. The use of acupuncture seems to be twice as common among the patients (16%) than among the doctors (eight percent). And further, there is no overall age or sex difference in the relation between trying acupuncture and being positive neither among doctors, nor within the general population (paper I, paper III). Given the perspective that acupuncture patient experience changes attitudes in a more positive direction, it is interesting to focus at some of the possible implications of this phenomenon.

As more and more people experience acupuncture therapy, intend to try it, or at least know someone else who has tried, the attitudes could be expected to turn in an even more positive direction in the future. Such perspectives become even more interesting, bearing in mind that only a small part of acupuncture patients experienced beneficial effects from acupuncture. Several acupuncture patients have instead a neutral or negative experience with regard to beneficial effect from the needling therapy. The association between positive attitudes and being an acupuncture patient could therefore be based on additional aspects than cure of the disease or relief of certain symptoms.

One could also presume that positive attitudes to acupuncture might partially depend on the belief that acupuncture has a low adverse effect rate. Ten percent in the general population had heard about acupuncture adverse effects (Paper III) and 12% among doctors have reported such events (Norheim, 1996b). For those who underwent acupuncture, seven percent had experienced minor adverse reactions, while no serious acupuncture adverse effects were noticed. However, people in general seemed to be well aware of the Norwegian patient who suffered fatal cardiac tamponade following acupuncture treatment (Paper IV). Even if low adverse effect rates might contribute to positive attitudes to acupuncture, this cannot fully explain the linkage between trying acupuncture and having a positive attitude.

The “setting” of the acupuncture therapy could have a special appeal to those who visit acupuncturists. In acupuncture therapy, much time is spent with the patient, and all major *and minor* symptoms and signs are important for the diagnosis and selection of acupuncture points. Therefore these patients could feel that their everyday problems are taken “more seriously” than within the conventional health care (Davidoff, 1998). An increasing proportion of the population even uses acupuncture to “prevent future illness from occurring or maintain health and vitality” (Eisenberg 1998). Acupuncture is reported to result in a broad range of outcomes from physical and emotional change through to wider benefits involving lifestyle, outlook and attitude towards their health status (Furnham, 1994; Gould, 2001).

Even if acupuncture has become a relatively common therapy among the myriad of therapeutic options, the use of acupuncture needles still might have an exotic appeal. The mechanisms in health and healing used in acupuncture could fulfil some patient’s expectations of “simple and natural” approaches to symptoms and disease. If these expectations are being met by the acupuncturist this could, at least in part, explain the linkage between trying acupuncture and having positive attitudes to the method as such.

The effect of trying acupuncture might, however, not have the same influence on attitudes to acupuncture among medical students today. Even though medical students in 2000 have tried, or intend to try acupuncture just as often as students in 1996, they still have achieved a more negative attitude in terms of recommending acupuncture for their future migraine patients. (Paper II; Nguyen, 2003).

5.3.1.3. The association between attitudes to acupuncture and level of professional health education

One of the trends uncovered in this present thesis is the fact that longer professional health education was associated with what could be regarded as an increasingly negative attitude towards acupuncture. The most experienced medical students and senior hospital doctors

seem to take a position quite different from the position of the patients they are serving or planning to serve.

To “believe in” the effects of acupuncture represents a paradigmatic shift, which for the time being requires the ability to let go of some of the well-established positions in evidence-based medicine. Acupuncture therapy is still primarily based on empiric knowledge and tradition. Every step “deeper into” conventional health care, and stronger emphasis on evidence-based medicine seems therefore to contribute to a further distance towards acupuncture. This could also possibly be a part of the explanation for doctors in research positions being even more negative to acupuncture than their colleagues working in hospitals (Salomonsen, 2004).

Working in hospitals or in research positions also implies that you encounter less patient feedback about acupuncture compared to colleagues in general practice or elsewhere outside health institutions. And further, hospital doctors probably more often than general practitioners are confronted with the most serious acupuncture adverse events since these problems usually are taken care of within the hospital environment.

A negative attitude towards acupuncture could also be a cohort phenomenon among medical students. The fact that students in 2000 tend to be more negative than students in 1996 could support this point of view. This explanation is, however, not very likely as shown in paper II. Studying medicine implies aging, but changes within four years as a medical student seem more likely to influence attitudes to acupuncture than aging on it’s own. Tradition and hierarchy might generate the role modelling discussed in paper II. It is still very likely that the opinions of the professor and chief surgeon have a strong influence on the thinking of the medical student and the young doctor. This socialisation could represent a strong and likely explanation for acquiring a so-called negative attitude to acupuncture.

5.3.1.4. The association between health status and acupuncture patient experience

Acupuncture patients suffer mainly from common complaints and have often tried to solve their health problems within conventional health care before turning to acupuncture. Those who visit the acupuncturist seem to be either those with greatest health problems, or at least those most concerned about own health. Acupuncture patients are also large-scale consumers of both conventional health care and unconventional health services other than acupuncture.

As acupuncture patients frequently visit their own doctor, they should be well monitored by the ordinary health care. Delayed doctor contact could be minimized, and the “hazards” of trying acupuncture kept under surveillance. Some of the patients who visit acupuncturists, feel they are not being helped within the ordinary health care system. Insufficient capacity and waiting lists might be the “driving force” for visiting an acupuncturist, not necessarily a deep-felt attraction to the acupuncture needle. The acupuncturists might therefore fill some of the gap between health care capacities on the one hand and patients’ needs and demands on the other hand. Acupuncture might from this perspective be considered a useful partner for the ordinary health service since this gap unfortunately is expected to increase.

It is also questionable whether the distinctive character of acupuncture is the main motivational force for trying the method. The intimate contact and time used by the therapist might be just as important as the specific needling. If this is the case it should have implications for the planning of the ordinary health care system. Efficiency in hospital

treatment is often measured in numbers treated, probably because patient satisfaction is not regarded important enough, and is also difficult to measure. However, if one of the solutions to complaints and discontented patients is to spend more time with the patient, why all the pressure to reorganize towards a more cost-effective health care system? There is certainly some potential for a more effective health care system. It is, however, possible that the satisfaction among hospital patients in the future will diminish, since less time is spent with the chronically ill patient.

Hospitals might not be the arena in which acupuncture in general should be performed. Maybe the totality of the current acupuncture treatment setting could be lost in an attempt to integrate acupuncture into the hospital treatment setting. The best thing might be to develop the uniqueness of the acupuncture treatment setting. This could potentially maximize patient benefit by them receiving more personal and prolonged care.

5.3.2. The role of acupuncture in health care - Where are we and where are we going?

Advances in modern health care have dramatically changed the therapeutic environment. Computer technology, laser-techniques, and future possible genetic engineering give us new health care perspectives, and evidence-based medicine is generally considered the ultimate therapeutic approach (Sackett, 1996b). Conventional health care as previously practiced, might have lost some of its perspectives. A consequence is, unfortunately, that family medicine in other countries is claimed to be not a healing, but a dying art (Charlton, 1995; Smith, 1996).

Patients seem necessarily not to be satisfied with the complexity of available conventional therapeutic measures (Astin, 1998a). There seems to be a persuasive appeal in alternative medicine that might be related to the power of shared beliefs between patient and practitioner (Kaptchuk, 1998a). The energetic perspective in acupuncture appeals to the concept of self-healing, and gives patients a much-needed sense of control (Davidoff, 1998), a clear expression of the “patient-centred” medicine (Laine, 1996).

However, there have, in general, also been changes in patients’ perceived needs and demands for health care. The old large family pattern has been subdivided into smaller units, the hours at work away from home in a family household has increased, and children are under professional supervision from their first year of living. In this kind of society many of the health-protective and health-promotive relations may have been lost. The results can be seen within the health care system as more and more concerns end up at the health therapist’s desk. Problems that previously were taken care of in the extended family setting are now brought into the professional health care (Turner, 1995).

In addition, complaints that previously were not considered to be medical problems are now more or less defined to be the responsibility of the health care system. Cosmetic surgery, infertility-treatment, high-tech sports medicine, and the coming genetic therapy are some of the new areas where patients could claim their rights according to our new definition of “being healthy”.

There is no reason to question the fact that some of the tools in modern conventional medicine have contributed substantially to a better health care for patients with serious and major

diseases. However, these modern therapeutic approaches might not be just as good in dealing with everyday problems like allergies, headache, back pain, fibromyalgia, sleep disorders, fatigue, and other “minor” health problems. Maybe the successful high-tech, modern medicine is inappropriate and insufficient for these and other vague complaints, health concerns, and “living problems”. Perhaps the human contact and encouragement is just as necessary as the specific treatment (Davidoff, 1998). Knowledge about adverse events and reports of mistreatment in conventional therapeutic practice might also have led to less confidence in the treatment offered (Brennan, 1991; Lazarau, 1998).

However, the patients who try acupuncture are not necessarily dissatisfied with orthodox medicine (Astin, 1998a; Paper IV). Those who seek help in acupuncture are rather those who also visit their medical doctor most frequently (Eisenberg, 1993; Paper IV). Acupuncture patients also use other alternative therapies, most often homeopathy and herbal therapy, more often than patients without acupuncture-treatment experience (Eisenberg, 1998; Paper IV).

And finally, the attractiveness to patients suggests that acupuncture might provide important clues to explain ways in which scientific medicine seems to be falling short (Davidoff, 1998). There might also be lessons to learn for conventional healthcare from acupuncture (Dalen, 1998). One of the most obvious principles in acupuncture is always taking the most optimistic possible view of clinical reality (Kaptchuk, 1998).

The apparent increased use of alternative medicine and acupuncture might also have other explanations. Maybe it has become more accepted to admit use of alternative medicine (Eisenberg, 1998). As more and more people try the method, patients might feel more confident being identified as a user of alternative medicine and acupuncture. If that is the case, the recent supposed increase in use of acupuncture might be a result of better registration and documentation.

To merge acupuncture/acupressure treatment into mainstream medicine is a challenge that warrants comprehensive consideration. The scientific documentation of acupressure in morning sickness has up to now been considered insufficient according to the demands of evidence-based practice. However, this is also the case for several well-known and commonly used therapeutic approaches within the conventional health care system. Current truth in medicine and medical therapy is an ever-changing story.

Coronary artery bypass was performed for at least two decades before it was scientifically supported by randomised clinical trials (Murphy, 1977). Percutaneous transluminal coronary angioplasty followed a similar course, demonstrating efficacy almost 20 years after its introduction (Parisi, 1992). Antithrombotic therapy has been used for a long time, but the documentation was at a low level for decades. The editor of the Archives of Internal Medicine therefore asks if warfarin, aspirin and heparin therefore should have been classified as alternative therapy (Dalen, 1998).

The label of alternative or unconventional might also be culture bound. The Navajo Indians in the Southwestern USA have integrated *unconventional* Western medicine that is provided by the Indian National Health Service, into their centuries-old *conventional* health care, which is provided by their native healers (Kim, 1998).

However, acupuncture might also be regarded as already, in part, being accepted in conventional health care (Paper II; Pirotta, 2000). Acupuncture has for the last two decades

been an available option in Norwegian outpatient pain clinics (Norheim, 1990), and the public seem to acknowledge acupuncture as a therapeutic option alongside conventional health care (Furnham, 2000). Family doctors' consideration of acupuncture treatment for own disease (Paper I), and their high referral rate to acupuncturists ensure that at least the GP's have confidence in this therapeutic option (Pirotta, 2000).

On the other hand, the Norwegian National Health Insurance does not cover acupuncture treatment, and the use of acupuncture is still controversial among the most experienced hospital doctors (Paper I). The doctor who views acupuncture as already integrated, could do so from a negative perspective. Maybe some of those holding this perspective regard integration of acupuncture as a process that has already gone to far?

Acupuncture is not integrated in conventional health care and education. The influence on young medical students from old role models will therefore maintain a general negative attitude (Paper II). It might, as a consequence be appropriate to introduce acupuncture and possibly other alternative therapies into the medical curriculum, as already done in many US medical schools (Wetzel, 1998). Increased interest in learning acupuncture among medical students in Tromsø in 2000 compared to 1996 might support this point of view (Nguyen, 2003).

Acupuncture has been practiced for centuries before the term evidence-based started to influence medical practice, and before randomised placebo-controlled trials were developed. The placebo concept has, however, been through a dramatic metamorphosis during the last 50 years. During the last decade, the placebo concept has even been accused of being an alibi for the use of RCTs to develop evidence-based medicine (Kaptchuk, 1998). Could it be that the unspecific effects in acupuncture therapy, and the art of medicine is impossible to quantify in terms of RCT and placebo? If acupuncture becomes a therapeutic measure offered alongside cosmetic surgery or genetic engineering, the Chinese method has definitely lost its virginity, purity, and perhaps also the exotic appeal. If being able to practice in a hospital is the ultimate goal of the acupuncturists, this might contribute to the downfall of their practice (Ernst, 1995).

Obviously, the double-blind RCT methodology using placebo control has contributed to great improvements in research and medical care. However, in acupuncture, one has to be very cautious about too persistent conclusions with regard to the usefulness for patients as the RCT methodology contributes knowledge only at two of the five levels of knowledge in the field. For a description of acupuncture, exploring the safety aspects, or basic knowledge about the mechanisms involved in the specific acupuncture response, the placebo- and RCT-context can hardly give the answer needed.

Therefore, the role of acupuncture in health care should perhaps not solely be based on scientific results gained in double-blind RCT methodology using placebo controls. But research using this methodology gives important information about efficacy of acupuncture. For future clinical efficacy research, we do not need alternative methodology. The main issue is to ask the "right" research question, and then apply the correct well-established research method to answer this question (Norheim, 2000).

Finally, the long-lasting common use of acupuncture tells us that for the role of acupuncture in health care for patients, and perhaps also for people working as health professionals, other aspects than RCTs might be important. For medical doctors in everyday practice, it is

important to remember and consider acupuncture, and perhaps also suggest this therapeutic option for patients in appropriate clinical situations.

5.3.3. The safety aspect in acupuncture therapy

To assess the risk of adverse effects in acupuncture, the terms *acupuncture* and *adverse effect* have to be clarified. Japanese “hari” and “okibari” (Murata, 1990), or self-puncture with sewing needles (Schiff, 1965) cannot be considered as mainstream acupuncture. The experience of transient discomfort like malaise, dizziness, light nausea, fever, pain in the punctured area, numbness and even increased pain seem to be inevitable in some patients. These events are in oriental medicine referred to as the “Menken phenomenon”, a kind of healing crisis suggesting a transient worsening of symptoms followed by improvement, and the classification as adverse effect is questionable (Yamashita, 1999; MacPherson, 1999a).

Among Norwegian acupuncturists, the adverse effect rate was estimated to be 0,21 complications for each year of full time practice (Norheim, 1996a), and the adverse event rate per consultation 0,0012. In an Australian study (Bensoussan, 1996), the overall number of adverse events per full time practice is 1,5 annually for all practitioners of Chinese herbal medicine and/or acupuncture. A significant lower rate of adverse events is found among the practitioners with more than 36 months of education compared to those practitioners with less than 12 months of education. The overall adverse event rate per consultation is found to be 0,0042. In a Japanese prospective study, 84 acupuncturists experienced 94 adverse events during 6 years of full time practice (Yamashita, 1999). The adverse effect rate was estimated to be 0,18 complications for each year of full time practice. The adverse event rate per consultation was found to be 0,0014.

Selection bias might have occurred in the Australian study (Bensoussan, 1996), as response rates were as low as 43% for non-medical practitioners, and only 18% for medical practitioners. Results from the major Japanese prospective study on acupuncture adverse effects (Yamashita, 1999) are also difficult to generalise for all acupuncturists. The therapists in this study had attended a special education programme to prevent adverse reactions. Increased focus on the adverse effects might contribute to less frequent occurrence than in a randomly chosen acupuncture practice elsewhere.

Acupuncture adverse effects in Norway were presented in an important paper published in 1996 (Norheim, 1996). It was one of the first scientific papers ever focusing on this important issue and has contributed to the international discussion of acupuncture adverse events. The paper is referred to in almost every subsequent publication dealing with acupuncture adverse effects.

The message in this early publication was first of all the presence and description of this phenomenon as presented in table 6 (p.70). And further, the study showed that data from both doctors and acupuncturists should be included as they might encounter different adverse events. However, these numbers have to be interpreted with caution, and the data provide a potential for underreporting (Norheim, 1996b).

A systematic registration of adverse effects during acupuncture treatment could contribute to the reduction of the problem. This registration would increase awareness about adverse effects in acupuncture, and could give feedback and advice on how to avoid future adverse events.

Common guidelines on how to minimise the risk should be a priority for the acupuncture profession. Specific educational programmes focusing on insertion technique (Ernst, 1997; MacPherson, 1999a) therapist's negligence (Yamashita, 1999), and length of education (Bensoussan, 1996) seem to prevent acupuncture adverse effects.

Table 6. Acupuncture adverse effects reported from 1135 randomly selected Norwegian doctors and 197 Norwegian acupuncturists (Norheim, 1996b).

Type of acupuncture adverse effect	Number of patients with acupuncture adverse effects reported by the acupuncturists	Number of patients with acupuncture adverse effects reported by the doctors
<i>Mechanical organ injury</i>		
Pneumothorax	8	25
Burns from moxa-therapy	1	3
Parestesia/numbness	1	-
Nerve injury	-	3
Forgotten needle	-	1
<i>Infections</i>		
Local skin infection	2	66
Perichondritis	-	16
Arthritis/Osteomyelitis	-	4
Endocarditis	-	2
Hepatitis (HBV)	-	1
Myositis	-	1
Peritonitis	-	1
Pleuraempyem	-	1
<i>Other adverse effects</i>		
Psychiatric problems	-	20
Fainting during treatment	132	10
Increased pain	25	31
Menstruation disturbance	1	2
Lymph oedema	2	-
Insomnia	1	-
Malaise	1	-
Angina pectoris	1	-
Epileptic seizure	1	-
Nausea/vomiting	25	-
Delayed "doctor-contact"	-	10
Chylothorax	-	3
Sweat hyper secretion	-	1
Triggered granulomatous infection	-	1
Total number of patients with acupuncture adverse effects	201	202

6. Conclusions

Unconventional therapies like acupuncture are widely available and commonly used by the public. Research in acupuncture should therefore utilize a slightly different research approach rather than the way pharmacological agents are invented and brought to the market.

According to a five-level research model, this thesis has described the position and role of acupuncture in terms of attitudes to and experience with the method among medical students, doctors and within the general population. Some data on level two regarding adverse effects are also included, and the clinical trial addresses issues at level four.

Specifically the thesis shows that:

- More than half of Norwegian doctors have already undergone acupuncture or indicate that they would consider to do so, almost 40% would recommend it to migraine patients and most doctors consider acupuncture already integrated in or would like to see acupuncture as an integral part of the public health care system.
- Students going through medical school appear to be influenced by the educational process to change their attitudes towards acupuncture in a negative direction.
- Three out of four in the general population have already undergone acupuncture or indicate that they consider to do so, the major part indicate effect and very few adverse events are reported. Acupuncture patients are either those with greatest health problems, or at least those most concerned about own health.
- Fifty seven percent of the four studied groups (Doctors, medical students, acupuncturists and population) indicated that the treatment effect seen in acupuncture is mainly a genuine acupuncture effect, and not a placebo response. Doctors and students express a more sceptic view than others, and having tried acupuncture for own health problems is significantly associated with a less sceptic view within all study groups.
- The hours of discomfort is significantly reduced by using acupressure for morning sickness in early pregnancy.

It is likely that acupuncture might play a useful role in future health care, being a therapeutic option widely accepted by doctors and currently commonly used by the public. Bearing this in mind, the present thesis might contribute to the basic knowledge about attitudes, practice and experience with acupuncture, necessary for future political and medical decision-making.

7. References

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