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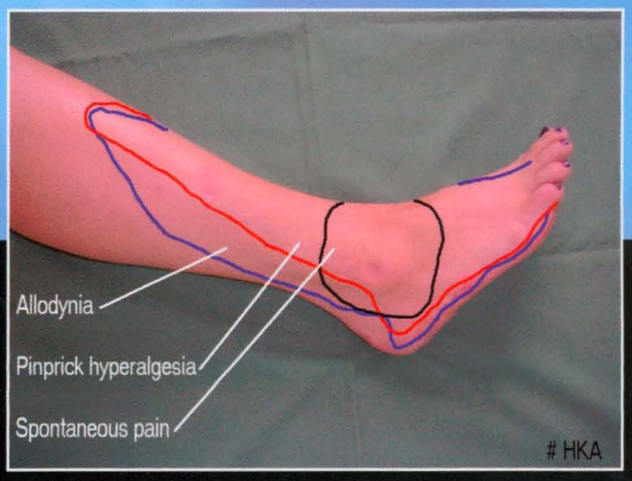
**ACUTE AND CHRONIC PAIN:
WHERE WE ARE AND WHERE WE HAVE TO GO**

Proceedings from the 1st San Matteo International Meeting on Pain Research (SIMPAR), October 3-4, 2008, Pavia, Italy



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Acute and Chronic Pain:
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Proceedings from the 1st San Matteo International Meeting on Pain Research (SIMPAR), October 3–4, 2008, Pavia, Italy

Guest Editors:

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Epidemiology and treatment of pain in Italy: part I

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Abstract

Chronic pain can be debilitating and often becomes the defining factor in patients' lives. Many trials have been developed to evaluate the extent and quality of pain in specific populations. The most important informations result from the study "Pain in Europe", published in 2006, that showed a prevalence of pain by 19%; low back pain was the most frequent disease; one third of the interviewed people complained the worst imaginable pain; on average, people lived with chronic pain for 7.7 years. In regard to the treatment of pain in Italy, the same survey shows inadequate treatment in 47% of cases; 42% of patients reported the assumption of drugs; in 68% of cases Italian doctors prescribed NSAIDs; no patient was in treatment with strong opioids. The link between the reduced use of opioids in Italy and the fear of physicians has been demonstrated by a recent study, not yet published, about the use of analgesics in emergency setting. It is reasonable to believe that the actual situation in Italy is the consequence of the lack of a specific school on pain therapy and of the teaching of pain therapy in the University, until a few years ago. In this situation, only the scientific societies can obtain results.

Keywords: Chronic pain; Pain treatment; Pain in Italy

Chronic pain is defined as a pain that persists for over 3 months and even indefinitely. It can be debilitating and often becomes the defining factor in patients' lives. Without relief, or the hope for relief, many patients lose the ability to eat, sleep, work and function normally: chronic pain can be a pervasive experience that interferes with daily life and has a substantial physical, psychological and social impact on patients (Argoff, 2003).

Because of the socio-economic implications of chronic pain, epidemiological investigations in Western countries have relevant importance.

Many trials have been developed to evaluate the extent and quality of pain in specific populations. Over the past 10 years, chronic pain has received increasing attention in health care, especially in relationship to patient well-being and quality of life, and chronic pain relief has become a global healthcare priority (Gore et al., 2007).

In Italy, few data are available. The most important informations result from the study "Pain in Europe", published in 2006, the largest trial ever made on chronic pain; it is a pan-European study, in which all the causes of chronic pain were analyzed (Breivik et al., 2006).

Objectives of this study were the following:

- to define the prevalence of chronic pain in Europe
- to understand and quantify the causes of chronic pain
- to explore all demographic aspects of suffering people
- to explore the impact of pain on the quality of life of the suffering people
- to understand the pharmacological and/or physical treatments and the levels of satisfaction
- to explore the attitude of the patients together with their experienced pain.

Interviews were made using the CATI system (Computer Assisted Telephone Interviewing), over the phone casual interviews.

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Prevalence data were extracted from more than 46,000 interviews. More specific data were extracted from at least 5000 interviews.

The investigation showed, for the European population, a prevalence of pain by 19%, of mild intensity in 13% of the people and of severe intensity in 6%.

Low back pain was the most frequent disease and main causes of chronic pain resulted arthritis and osteoarthritis (34%). Pain was related to movement in the 76% of cases. One third of the interviewed people complained the worst imaginable pain.

The prevalence of pain was greater in Norway, Poland and Italy, while Spain was the less affected country, even though prevalence was higher than one of ten (11%). In 1/3 of all European families, at least one case of chronic pain was found.

In Italy, 3849 screening phone calls and 300 more specific interviews were made. The prevalence of chronic pain resulted of 26%. About the half of the Italian women complained chronic pain (49%). The regional prevalence of pain was the following:

- North West: 27.7%
- North East: 20.9%
- North/Center: 32.2 %
- South/Center: 24.1%
- South: 21.7%

On average, people interviewed lived with chronic pain for 7.7 years. Almost 1/5 lived with pain for more than 20 years.

Data from this survey are alarming, especially if a future perspective is considered.

A major shift in the age distribution of the world population is now taking place. In developed countries, the percentage of the population over 65 years will rise from 17.5% to 36.3% by 2050 and the over-80 age group will be more than triple (US Bureau of the Census, International Data, 2002).

In Italy, people over 60 years, which were approximately 6 million in 1950, (1950–1990) have almost doubled over forty years. According to the United Nations (UN, 1993), they should reach almost 16 million in 2020, equivalent to 29.3% of the total population. The numerical exchange young–old has happened in 1995, the first country in the history of humanity; during the twenty-first century, it will occur for all other countries (Lori et al., 1995).

With the increase of average age, the problem of pain will raise, as chronic pain affects more than 50% of older people living in the community setting and more than 80% of nursing home residents (Ferrell et al., 1995, Helme and Gibson, 2001).

Older persons are more likely to suffer from chronic pain than younger ones, as referred by 73% of community-dwelling older people (Brody and Kleban, 1983). Pain tends to be constant, of moderate–severe intensity, lasting for several years, multifocal and multifactorial (Brattberg et al., 1996).

Of older persons admitted to the hospital, 45.8% reports pain; 19% has moderately or extremely severe pain; 12.9% is dissatisfied with his own pain control (Desbiens et al., 1997).

In regard to the epidemiology of cancer in Italy, data referred to 1990 show 120000 new cases in males and 102000 in females, with an incidence rate of 390/100000 and 310/100000 respectively. With regards to the mortality, the annual number of deaths by cancer, in the 3 years 1989–1991, was approximately 85000 males and 60000 females (data from Oncology Center of Aviano, Italy, 1991).

Results from international studies show that 30% of the patients claims pain at diagnosis and 65–85% at advanced states (Zhukovsky et al., 1995; Coyle et al., 1990, Grond et al., 1994, 1996). Considering that the cancer mortality is 145000 patients per year, the number of patients with pain exceeds 100000.

In regard to the treatment of pain in Italy, the same survey on pain in Europe shows inadequate treatment in 47% of cases.

In regards to the pharmacological treatment of pain, 42% of patients reported the assumption of drugs, 55% began to take them but stopped therapy, 22% never started therapy, 23% was taking medications. These data indicated a lack of confidence and poor compliance with prescribed therapy.

In 68% of cases Italian doctors prescribed NSAIDs, 9% weak opioids, 6% paracetamol, 7% COX_2 inhibitors. No patient was in treatment with strong opioids. In 2003, consumption of morphine was 4mg/year per person in Italy, which results the last nation for consumption of opioids in Europe. Compared to the rest of Europe, is striking the high consumption of NSAIDs, unlike that of paracetamol.

It is current opinion that the limited use of opioids is linked, in Italy, to religious reasons too, as the Catholic Church, until some decades ago, was against the use of morphine in the treatment of pain.

A problem, which in the past complicated the use of these drugs, is the difficulty of prescription, because of formalities to carry out and the strict regulation, together with legal problems arising from the actual or perceived abuse or addiction to them, even though it has been refuted by the international scientific literature.

Recently the modality of prescription of opioids has been simplified, but it is still different from that of other medicines, supporting the idea of opioids as special and hazardous drugs.

Consequently, in Italy is frequent that a terminal cancer patient, affected by severe pain, is treated with massive doses of anti-inflammatory drugs or weak opioids, but not strong opioids or invasive therapies (Marinangeli et al., 2004). The first two steps of the WHO guidelines are formally respected, but not the last one, thus raising the following issues regarding appropriate therapy:

- is it reasonable to administer massive doses of NSAIDs or weak opioids in order to avoid strong opioids, thus

achieving relative efficacy with a potentially greater incidence of side effects?
- what is the rationale for starting therapy in terminal patients with the weakest analgesic agents, avoiding stronger more effective drugs?

The study of Marinangeli et al. was very important to convince Italian physicians to use strong opioids in cancer pain.

Today we are trying to convince them to skip the second step of WHO, when the patient is affected by a progressive disease, as side effects of weak and strong opioids are similar (Eisenberg et al., 2005).

Another major challenge is to convince Italian physicians that pain can be severe even in chronic non cancer diseases and it should be treated with adequate drugs.

There is an evident discrepancy between Italy's commitment to the discipline of pain therapy, in terms of publications and initiatives, and insufficient results, in terms of correct use of analgesics.

The link between the reduced use of opioids in Italy and the fear of physicians has been demonstrated by a recent study, not yet published, about the use of analgesics in emergency setting. Despite the morphine is a drug of first line treatment of acute heart disease, in many ambulances or helicopters strong opioids are not available (Marinangeli et al., 2008).

It is reasonable to believe that the actual situation in Italy is the consequence of the lack of a specific school on pain therapy and of the teaching of pain therapy in the University, until a few years ago.

In this situation, only the scientific societies can obtain results.

The Italian Association for the Study of Pain (Associazione Italiana per lo Studio del Dolore – AISD), in conjunction with EFIC (European Federation of IASP Chapters) is working to spread the culture of pain with frequent cultural initiatives.

AISD is trying to create a network of pain centres, to give greater visibility to discipline, as in Italy there is still the lack of adequate organization and visibility of the pain centres inside the hospitals. Many patients still ignore that there is a medical specialist in pain therapy.

In 2001 was promulgated in Italy a special law to combat the pain in hospitals, entitled: "Hospital without pain". To date, very few hospitals have adopted the rules of this legislation.

AISD, in the last 5 years, has largely grown, what makes us optimistic for the future.

Conflict of interest statement

The authors state that no financial and personal relationships with other people or organisations that could inappropriately influence their work exist. The authors declare that no potential conflicts of interest (such as employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding) exist.

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Epidemiology and treatment of pain in Italy: part II

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Abstract

Pain relief is a branch of Medicine that only recently has developed, its institutional standardization levels and its process standards have not yet been identified. Pain therapy was first introduced by Bonica in 1951, but is still disregarded in many cases, despite the consciousness that the lack of pain control causes evident damage and has a significant effect on well-being perception. The primary need for not suffering from unnecessary pain is undervalued, as a result of a multiplicity of factors. In order to improve this situation, the "Pain-Free Hospital" (PFH) program was instituted, with the specific aims of increasing the awareness of pain incidence, directing the attention of general population and caregivers to the "pain issue" and making the necessary treatments available. According to the agreement drawn up by the Governmental-Regional Conference in 2001, the PFH program was instituted in Italy and, in conformity with their own Regional health care strategy, some Italian Regions planned the foundation of a Network of Pain Therapy Centres. Numerous laws have been introduced for the development of pain therapy and Pain Therapy centres in Italy, at both national and regional level. A survey made in 2001 showed that 232 centres of Pain Therapy and Palliative Care, 16 Palliative Care centres and 76 Pain Therapy centres were active in Italy. A network of Italian registers, monitoring the activity of pain care professionals, is developing in order to guarantee quality and safety of pain therapies.

Keywords: Chronic pain; Pain treatment; Pain in Italy

1. Background and institutional organisation in Italy

Pain relief is a branch of Medicine that only recently has developed, its institutional standardization levels and its process standards have not yet been identified. To facilitate the organization and the growth of Pain Relief Centers, both institutional regulations (Weissman et al., 1997) and a strong cohesion among the professional figures are required. Moreover, professional figures must identify their own standard and control levels for the care process (Coluzzi and Pappagallo, 2005) and, since opioids are the gold standard in pain therapy (Coluzzi and Pappagallo, 2005), the levels of safety and efficacy of these drugs should be analyzed.

Pain therapy was first introduced by Bonica in 1951 (Bonica, 1990), but is still disregarded in many cases, despite the progresses made to understand the antinociceptive system (Besson, 1999) and the consciousness that the lack of pain control causes evident damage and has a significant effect on well-being perception (Gureje et al., 1998).

It should be noted that there is a high incidence of pain in the general population (Crook et al., 1984) and in-patients of health care facilities (70–80%) (Donovan et al., 1987).

The comprehension of the complexity of pain management is crucial for health organisations and it is linked to professional (Hamilton and Edgar, 1992) and organisational knowledge.

The primary need for not suffering from unnecessary pain is undervalued (Lebovits et al., 1997), as a result of

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a multiplicity of factors: biological underestimation, lack of specific knowledge, persistence of personal myths about opioids, personal pain perception and underestimation of risks and damages of chronic pain (American Pain Society Quality of Care Committee, 1995).

In order to improve this situation, the "Pain-Free Hospital" (PFH) program was instituted, with the specific aims of increasing the awareness of pain incidence, directing the attention of general population and caregivers to the "pain issue" and making the necessary treatments available (Besner and Rapin, 1993).

According to the agreement drawn up by the Governmental-Regional Conference in 2001, the PFH program was instituted in Italy and, in conformity with their own Regional health care strategy, some Italian Regions planned the foundation of a Network of Pain Therapy Centres. Since then, only sporadic and locally-centred researches were carried out on pain treatment; one of them was carried out by Costantini in 29 public hospitals of the Region Liguria: it analysed the complexity of a regional health service in Italy and showed an incidence of pain of 56.6% for in-patients (Costantini et al., 2000).

Numerous laws have been introduced for the development of Pain Therapy and Pain Therapy centres in Italy, at both national (Ministerial Decree 26/05/04, Analysis of Public Health 2001) and regional level (Emilia-Romagna Region).

A survey made in 2001 showed that 232 centres of Pain Therapy and Palliative Care, 16 Palliative Care centres and 76 Pain Therapy centres were active in Italy (Annuals of Public Health, 2001).

In regard to the organisation of Pain Therapy centres, a network of Italian registers, monitoring the activity of pain care professionals, is developing in order to guarantee quality and safety of pain therapies (Benchmarking, 2005).

2. Epidemiology of two specific pain conditions: pain in the elderly and low back pain

Pain is a very common issue among elderly, with a prevalence that varies from 25% to 80% in relation to age, support setting and type of the population. Pain prevents the normal course of daily activities in 25% of old persons. An Italian study (Landi et al., 2001), conducted on elderly assisted at home in the national territory, shows that more than 40% of people, older than 65 years, complains a daily pain that interferes with the common activities of daily living. These data refute the assumption that there is a reduction of pain perception and intensity in old age.

Several epidemiological studies seem to indicate that acute pain of recent onset decreases, whereas acute pain of non-recent observation increases, with the increasing of the age (Harkins, 1977). The visits for pain of recent onset reach a peak in the fifth decade of life, while outpatient visits for chronic pain increase linearly up to 65 years and then decreases slightly from 65 years onwards (Koch, 1993).

It is relevant that clinical conditions which more often cause chronic pain in young/adult people (migraine, headache, ulcerative disease, abdominal pain, back pain) decrease in old age, whereas chronic pain associated with muscle–skeletal degenerative processes, bone fractures, cardiovascular system and Herpes zoster increases in elderly (Marsland et al., 1976).

The chronic pain and the resulting disability are among the most important causes of poor quality of life, reduced well-being and depression in elderly patients (Ferrel et al., 1990); moreover, in a study conducted in 1306 elderly, it is reported that chronic muscle–skeletal pain is an important factor of disability (Scudds and McRobertson, 1998).

In regard to cancer pain, it does not seem to be significant differences in intensity and possible presence of neuropathic or incidental acute pain in the different groups of age observed. The elderly, however, as recently revealed, seem to require smaller quantities of opioids, compared the young–adult patients for analgesia (Vigano et al., 1998).

Low back pain is the most common disease in developed countries, affecting 70% of people during their life; 70% of adults has isolated episodes of low back pain yearly and 30–40% of them requires drugs or a withdrawal from work (Melzack, 1965).

Chronic low back pain is the results of injuries in 13% of patients. In 20% of the cases it causes work interruptions (Morisot, 1976); the probability of going back to work is inversely correlated with the period of work suspension due to pain.

Several studies have highlighted that the prolonged interruption of work is substantially negative for the patient and its resumption represents a factor of healing; it is relevant that 85% of patients were able to resume their work even after treatment with placebo.

A pain treatment involving a large number of drugs may lead to disability and a global rehabilitation program is required for some patients, which should either be accompanied by adequate social and professional treatments, to prevent the progression of pain to the chronic state (Waddel, 1996).

Nowadays this disease, which afflicts the population of working age, is considered the most expensive non-malignat disease that burdens on the Health System of North America (Chatani, 1995). In Europe 30–40% of adults (Clinical Standards Advisory Group, 1994) suffers from low back pain, which requires drugs intake or temporary suspension from work; 2% of this population suffers for over a year (Noguchi and Kowalski, 1991).

Low back pain represents the great health enigma of the twentieth century and the lack of adequate therapies amplifiers the expenses for disability.

The highest health costs are related to acute pathological forms, which are secondary to disk/radicular disorders, or to severe chronic pain, as the patients require frequent special-

ist visits and, eventually, numerous surgical interventions, even invasive.

The painful condition which is secondary to surgical intervention on the spine is defined "failed back surgery syndrome" (FBSS). The FBSS affects from 5 to 30% of patients (Wiltse et al., 1993), who have been submitted to previous surgery on the spine, regardless of the initial pathology.

3. Cancer pain: the WHO validation

More than nine million of patients in the world suffer from cancer pain, as a result of the disease itself or its treatment (Bonica, 1990).

The WHO Committee of experts on treatment of pain (WHO, 1990) stated in 1990 that "every patient suffering cancer has the right to be relieved from pain and to have the necessary therapy to guarantee the above right" (IASP and EFIC Declaration and Fact Sheet, 2004).

More than 20 years after the introduction of the pain ladder by the WHO in 1986, pain is not yet controlled in 40–45% of cancer patients. Major improvements in cancer pain therapy have been made (WHO, 1990) and, now, there is the consciousness that adequate pain control is a prerequisite for reducing suffering.

However, despite safe and effective treatments are available to control most types of cancer pain, there is still evidence of significant world-wide under-treatments (Lesage and Portenoy, 1999), which causes unnecessary sufferance and has relevant consequences for both patients and their caregivers.

Major barriers to effective cancer pain management include inadequate training of physicians in pain control, absence of a focus on the disease process rather than on patients' symptoms and poor use of opioids (Zaza and Baine, 2002). Moreover, neglecting psychosocial factors, such as psychological distress, social support and coping strategies can influence the patient condition and improve pain.

This serious condition of pain leads to severe physical disability and to an unbearable life for millions of European citizens.

Cancer Epidemiology: there are 1,292,000 new cases/year in Europe (2nd edition OMS, 1996); of these 270,000 are in Italy, including 165,000 (61%) people older than 65 years, of which 90,000 (33%) between 65 and 74 years old and 75,000 (28%) older than 75 years (Lyman, 1998); moreover the advanced phase of the disease is experienced by 150,000 people in Italy (Landefeld et al., 1995).

Nowadays, despite the huge human-economic cost of this epidemic, it is not yet completely understood the physiopathology basis of this pain, if there are phenotypic and/or genetic elements that are predisposing for cancer pain and which is the prevalent type of pain.

The European Society for Medical Oncology (ESMO) instituted a Guideline of Minimum Clinical Recommendations for the management of cancer pain in December 2004. According to this guideline, all patients should be evaluated for the presence of pain at each visit and a step-wise escalation of analgesic therapy should usually follow the 'pain ladder' as described by the WHO (Jost, 2005).

Cancer pain appears to be a predictor of survival, it seems to be a clinically important indicator of cancer progression (Twycross, 2003) and its immunosuppressive effects may enhance the disease progression (Page et al., 1997). Cancer pain and its therapy are influenced and influence many other cancer-related symptoms, so, for example, pain can disturb the sleep and hence have a negative impact on everyday life.

4. Opioids in Italy

Opioids are currently thought to be the most powerful and efficacious analgesics for the control of acute and chronic malignant and non-malignant pain. Nonetheless there are still many unresolved issues, such as if there is an opioid of first choice and how to determine its most suitable dosage (Coluzzi and Pappagallo, 2005). Opioid use in Italy is lower than in other European countries and the resistance versus these drugs for the treatment of non-cancer pain is even greater, mainly because of fear about the ease and safety of their management (Mercadante, 2006, Michna et al., 2004).

The usefulness of different opioids for the treatment of non-cancer pain is well documented (Kalso, 2005), as well as their best way of administration (Kalso et al., 2004), clinical efficacy (particularly for neuropathic pain – Dworkin et al., 2003), tolerability, safety and management (Banwarth, 1990).

Some authors (Coluzzi and Pappagallo, 2005) affirm that there is no first choice opioid and state that the first type of opioid to be used must be evaluated on the basis of the experience of the clinician, the co-morbidity of the patient and the pharmacological characteristics of the molecule.

The Institute of Algological Science (ISAL) and the Society for the co-ordination of Italian Antalgic Therapy and Palliative Care Centers (FederDolore) started the creation of an Italian Register for the Correct Use of the Opioids in 2004 (Amato et al., 2005), in order to assess the appropriateness and safety of opioids in Italy.

The development of guidelines is not sufficient to induce a change in physicians behavior, particularly when deeply rooted habits and beliefs are involved (De Conno et al., 2005).

In regard to pain relief, the need for professional training and initiatives to increase physicians (including specialists) familiarity with the use of opioids has been highlighted, as they are the major resource for the treatment of moderate–severe pain.

The Project of "Italian Register for the Correct Use of Opioids" was set up in this is context, with the purpose of training physicians, promoting the correct use of opioids and diffusing adequate tools for the pain management of outpatients.

Conflict of interest statement

All authors have no competing financial interests with other people or organisations that could inappropriately influence (bias) their work.

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