Acupuncture as a complementary therapy in patients with cancer: the experience of a Regional Public Health Service in Italy

Giuseppe Lupi MD

President of SIRAA - Italian Society of Reflex therapy, Acupuncture and Auricolotherapy
Visiting Professor of Zhejiang Chinese Medical University-Hangzhou Cina
ARTOI - Italian Association for Researches in Integrated Oncology
FISA - Italian Federation of the Acupuncture Societies

www.centromedicoagopuntura.it
Diffusion of Acupuncture therapy among Italian population

- According to the ISTAT official survey carried out in 2005, 1.8% of the Italian population followed an Acupuncture treatment.

- With regard to the success obtained thanks to Acupuncture treatments:
  - 61.1% of patients are satisfied.
  - 18.6% of patients are partially satisfied.

The results obtained are considered to be successful as the diseases treated are in most cases chronic and the western medicines have not sorted positive results.
Acupuncture PubMed Publications: 1980 to present
Publications on Acupuncture

PubMed search with “acupuncture” (05/2016):
24,674 publications
2013: 1,549 publications
2014: 1,767 publications
2015: 1,620 publications

PubMed search with “acupuncture and cancer”:
1,298 publications (5/2016)
2014: 115 publications (21 Review)
2015: 123 publications (19 Review)
Acupuncture in cancer patients

➢ To manage cancer-related symptoms, treat side effects induced by chemotherapy or radiation therapy and patient quality of life:
  ✓ Cancer pain
  ✓ Chemotherapy-induced nausea and vomiting
  ✓ Radiation-induced xerostomia, rectitis, dysphonia, weight loss, cough, thoracodynia, hemoptysis, fever, esophageal obstruction, poor appetite, night sweats, hot flashes, dizziness, fatigue, anxiety and depression

➢ To boost blood cell count, and enhance lymphocyte and natural killer (NK) cell activity
Acupuncture in cancer patients

• To manage cancer-related symptoms, treat side effects induced by chemotherapy or radiation therapy and patient quality of life:

Use of CAM in cancer across Europe

Molassiotis et al, Annals of Oncology, 2005; 2006
The MTC is a discipline with different therapies

- Acupuncture
- Herbal Medicine
- Massage/Tuina
- Qigong/Taiqiquan
- Diet therapy
Mechanism

- Acting on areas of the brain known to reduce sensitivity to pain and stress (Hui 2010; Hui 2009)
- Regulating neurotransmitters (or their modulators) and hormones (Cheng 2009; Zhou 2008)
- Increasing the release of adenosine, which has antinociceptive properties (Goldman 2010)
- Stimulating endogenous opioids production (Arranz 2007)
- Reducing inflammation, by promoting release of vascular and immunomodulatory factors (Kavoussi 2007, Zijlstra 2003)
- Increasing levels of T lymphocyte subsets (Zhao 2010)
- Enhancing levels of vasoactive intestinal polypeptide and calcitonin gene-related peptide (O’ Sullivan 2010), which may relieve xerostomia and hot flushes
Reliable efficacy on quality of life

Several studies conducted in leading European and American cancer centres to investigate other aspects (for example pain, nausea, constipation, edema) showed an improvement in the quality of life (sharp decrease fatigue, improving the quality of sleep, decrease of generalized anxiety and somatized…) Although it was no the aim of the study.

Acupuncture as Palliative Therapy for Physical Symptoms and Quality of Life for Advanced Cancer Patients

E. Dean-Clower; Integrative Cancer Therapies, 2010; 9(2) 158–167

- Acupuncture as palliative therapy to patients with advanced cancer on symptoms and quality of life (QoL)
- Improvement in anxiety, fatigue, pain, and depression
- QoL measures of pain severity and interference, physical and psychological distress, life satisfaction, and mood states showed improved scores during treatment, with sustained benefit at 12 weeks
What is the evidence for the use of acupuncture as an intervention for symptom management in cancer supportive and palliative care: an integrative overview of reviews

P. Towler • A. Molassiotis • S. G. Brearley

- 17 reviews were included in the review.
- Evidence was found for the use of acupuncture for treatment related nausea and vomiting
- Benefit was reported for other cancer-related symptoms, including pain, fatigue, hot flashes, xerostomia, dyspnoea and anxiety.
- Reviewers found a paucity of rigorous trials and heterogeneity of populations

Acupuncture should be considered for symptom management where there are limited treatment options, using current peer-reviewed guidelines and clinical reasoning.

Garcia MK, McQuade J, Haddad R et al.

- The purpose of this review was to evaluate the efficacy of acupuncture for symptom management in patients with cancer.
- A total of 2,151 publications were screened. Of those, 41 RCTs involving eight symptoms (pain, nausea, hot flashes, fatigue, radiation-induced xerostomia, prolonged postoperative ileus, anxiety/mood disorders, and sleep disturbance) met all inclusion criteria.
- Acupuncture is an appropriate adjunctive treatment for chemotherapy-induced nausea/vomiting, but additional studies are needed.
To summarise the evidence on the cost-effectiveness of acupuncture.

We identified full economic evaluations such as cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA) alongside randomised controlled trials (RCTs).

Of 17 included studies, 9 were CUAs that measured quality-adjusted life years (QALYs) and 8 were CEAs that assessed effectiveness of acupuncture based on improvements in clinical symptoms. All CUAs showed that acupuncture with or without usual care was cost-effective compared with waiting list control or usual care alone.

Overall, this review demonstrates the cost-effectiveness of acupuncture. Despite such promising results, any generalisation of these results needs to be made with caution given the diversity of diseases and the different status of acupuncture in the various countries.
Acupuncture in cancer patients

- Nausea Vomiting
- Pain
- Dry mouth
- Hot flashes
- Anxiety
- Insomnia
- GI dysfunction
- Lymphedema
- Fatigue
- Neuropathy
The 1997 National Institutes of Health (NIH) Consensus Statement indicated that “promising results have emerged . . . showing efficacy of acupuncture in adult post-operative and chemotherapy nausea and vomiting.”

- Based on 33 controlled trials
  - 27 showed positive results in favour of acupuncture, electro-acupuncture, or acupressure
  - The acupuncture point, PC6 had been the point used in most of the trials
• **1997 NIH** “Promising results have emerged... showing efficacy of acupuncture in adult post-operative and chemotherapy nausea and vomiting.”

• **1999 WHO** Acupuncture: review and analysis of reports on controlled clinical trials. Acupuncture has uses in cancer treatments, one is to relieve cancer pain and the other is to control the adverse reactions to radiotherapy and chemotherapy.

• **2009** Overview of Cochrane reviews of acupuncture. The conditions that are mostsolidly backed up by evidence are chemotherapy-induced and post-operative nausea/vomiting, and headache.
CINV - Background

- Chemotherapy-induced nausea and vomiting (CINV) is one of the most common and feared side effects of chemotherapy.
- Clinical evidence gathered to date has been favourable.
- Acupuncture is a safe medical procedure with minimal side effects.
CINV and Acupuncture

Conclusions

- The effect of acupuncture on chemotherapy-induced nausea and vomiting has been studied over the past 20 years, and clinical evidence gathered to date has been favourable (*Bao 2009*).
- Current practice guidelines recommend acupuncture as a complementary therapy for uncontrolled nausea and vomiting induced by chemotherapy.
Acupuncture is thought to be a very cost-effective therapy for nausea control in patients receiving chemotherapy compared with hospitalization and expensive intravenous medications for the intractable nausea, dehydration, and electrolyte abnormalities these patients might experience.

However, formal studies need to be carried out to assess the cost-effectiveness of acupuncture in addition to the newer pharmacological antiemetic regimens in these patients.
30/12/2002
The Government of Aosta Valley Autonomous Region decides to open a Regional Public Health Service to use Acupuncture
Goal

- Identify the acupuncture application fields scientifically validated that could be useful to the population to be included in a draft study within the benefits provided by the SSR.

- Evaluate the use of the Service and the level of satisfaction of the population through the number of Acupuncture sessions executed.
Projects must be:
• Evidence Based Medicine
• Useful for the population

Identified 2 areas

Musculoskeletal disorders
  **Pros:** popular demand by citizens and vast field of action
  **Cons:** high number of users, hard to handle

Cancer related symptoms
  **Pros:** patients with symptoms that are difficult to treat pharmacologically
  **Cons:** requires collaboration with oncologists, doctor’s offices, time and staff
01/05/2003

The Government of Aosta Valley Autonomous Region programmed an experimental project to treat cancer patients affected by specific pathologies due to cancer himself or chemotherapy side effects and pregnancy-induced nausea and vomiting.
12 years experience of a Public Health Service

- A retrospective study was carried out of the medical records of all patients treated with acupuncture for nausea and vomiting from May 2003 to July 2015.
- Data of all patients were identified by one of the authors (MC), not involved in treatment to reduce measurement bias, from the clinic's paper records and then analysed.
- They were outpatients with a history of troublesome nausea and/or vomiting during following previous cancer chemotherapy, who were referred to the hospital acupuncture clinic by the oncologist or the general medicine doctors.
12 years experience of a Public Health Service

- Retrospective survey → medical records of all patients treated with acupuncture from May 2003 to July 2015
- Five hundred and eighty (580) patients were identified and pertinent data were noted down digitally
- Total working days: 1498
- N. acupuncturist: 1
- Total acupuncture sessions: 11336
Acupuncture: 12 years experience of a Public Health Service

- Retrospective survey → medical records of all cancer patients treated with acupuncture for CINV and other chemotherapy side effects from May 2003 to July 2015
- Four hundred and fifty two (452) patients were identified and pertinent data were noted down digitally
- Total acupuncture sessions: 10.052
Treatment protocol

The acupuncture treatment was individualized to each patient according to the theory of Chinese Medicine

- Needles: disposable 0.25 x 25-40 mm

- **CINV**
  - KT: pre KT e post KT (PC6, CV12, SP4, ST36)
  - Next week: 2 sessions/week (PC6, CV12, SP4, ST36)
  - Recovery weeks between KT: 1 session/week (BL15, BL20, BL21)
  - Additional points: ST-AU
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<th>Patients/years</th>
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</tr>
<tr>
<td>2012</td>
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<td>2007</td>
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<tr>
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## Sessions/day

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<td>Max</td>
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Typical spectrum distribution of cancers

- Breast cancer (around 40%)
- Uro-genital tract cancers (around 20%)
- Gastrointestinal tract cancers (around 20%)
- Other types included respiratory tract cancers, head and neck cancers, gynaecological malignancies, and lymphomas.
Age

Age in the cancer group

<table>
<thead>
<tr>
<th>Mean</th>
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<th>Std Dev</th>
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<th>Max</th>
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<td>54.88</td>
<td>55</td>
<td>13.06</td>
<td>19</td>
<td>84</td>
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452 patients

- Female: 340 (79%)
- Male: 112 (21%)
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<tr>
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<td>Max</td>
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### Sessions per patient

<table>
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<tr>
<th>Count</th>
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<td>≤ 5 sessions</td>
<td>75</td>
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<tr>
<td>≥ 6 sessions</td>
<td>377</td>
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![Pie chart showing sessions per patient]
## Range sessions per patient

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<th>Count</th>
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<td>≤ 5</td>
<td>75</td>
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<tr>
<td>≥ 6 a 12</td>
<td>93</td>
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<td>≥ 13 a 20</td>
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<td>≥ 20 a 30</td>
<td>93</td>
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<tr>
<td>≥ 30</td>
<td>87</td>
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Years of treatments

Some patients continued their acupuncture sessions for more than one year coming back to our clinic in rare case till 4 years. The majority of patients, however, have been on treatment for 1-2 years.

<table>
<thead>
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<th>Years of acupuncture treatment</th>
<th>Patients</th>
<th>%</th>
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<tbody>
<tr>
<td>1 year</td>
<td>271</td>
<td>62,241</td>
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<tr>
<td>2 years</td>
<td>151</td>
<td>34,025</td>
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<tr>
<td>3 years</td>
<td>21</td>
<td>2,905</td>
</tr>
<tr>
<td>4 years</td>
<td>9</td>
<td>0,830</td>
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Subjective responses

- The subjective response (a reduced severity, especially duration, of nausea, as well as the number of bouts of vomiting) was almost universal in our cohort while receiving acupuncture.

- Most of the patients were enthusiastic about the outcome and requested further treatment.

- Many patients were keen to continue with acupuncture even if they only had a 30%-50% reduction in nausea and vomiting because they felt that the improvement significantly enhanced their quality of life.

- There were no side effects attributable to acupuncture and no patient 'dropped out' owing to this treatment.
Subjective responses

• Our patients cited numerous reasons for undertaking and being satisfied about acupuncture treatments including to reduce physical distress, fatigue, anxiety, depression, sleep disturbance, nausea, weight change, diminished concentration, and pain.

• These results positively influenced the wellbeing of the patients, permitting them to return to some of their daily life activities and reducing their feeling of incapacity.

• Most patients said they would repeat acupuncture or recommend it to someone they know for a similar condition.
Conclusions

• To the best of our knowledge, this is the first study about the use of acupuncture by cancer patients in Italy by means of a public approach with the support of the Regional Sanitary Service (SSR) (Aosta Valley Region). Especially considering the very large number of patients treated and of acupuncture sessions carried out.

• Acupuncture was able to manage symptoms that worsen a cancer patient’s quality of life: nausea, vomiting, fatigue, pain, anxiety.
Observational study on the effect of acupuncture in the prevention and treatment of oral mucositis
Mucositis

- One of cancer therapy side effects that remain a major source of illness despite the use of a variety of agents to prevent them.
- Oral mucositis represents a major non-hematologic complication of cytotoxic chemotherapy and radiotherapy associated with significant morbidity: pain, odynodysphagia, dysgeusia, and subsequent dehydration and malnutrition reduce the quality of life of affected patients.
Observational study on the effect of acupuncture in the prevention and treatment of oral mucositis

- Observational study → medical records of all patients treated with acupuncture from 2008 (included) to July 2013
- Two hundred and eighty (280) patients were identified
- No pts with < 6 sessions or > 20 sessions
- Total: 125 patients
Sex and age of 125 patients

- Female: 100 (80%)
- Male: 25 (20%)

Age

<table>
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<tr>
<th>Mean</th>
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<th>Std Dev</th>
<th>Min</th>
<th>Max</th>
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<tr>
<td>53.62</td>
<td>54</td>
<td>13.66</td>
<td>26</td>
<td>78</td>
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### Number of sessions

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<tbody>
<tr>
<td><strong>Mean</strong></td>
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<td><strong>Median</strong></td>
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<td>6</td>
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<td><strong>Max</strong></td>
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## Mucositis Incidence

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
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<tbody>
<tr>
<td>No mucositis</td>
<td>76</td>
<td>60.80</td>
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<tr>
<td>Yes mucositis</td>
<td>49</td>
<td>39.20</td>
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## Mucositis incidence

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<tr>
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<tbody>
<tr>
<td>Female</td>
<td>62</td>
<td>38</td>
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<tr>
<td></td>
<td>62%</td>
<td>38%</td>
</tr>
<tr>
<td>Male</td>
<td>14</td>
<td>11</td>
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<tr>
<td></td>
<td>56%</td>
<td>44%</td>
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NS
## Number of sessions

<table>
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<td>4.31</td>
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<tr>
<td>Yes mucositis</td>
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<td>11</td>
<td>4.20</td>
<td>6</td>
<td>19</td>
</tr>
</tbody>
</table>

NS
Results

• Mucositis incidence from the literature: 40-80% → 60%

• Aosta mucositis incidence: 39,2%

• The incidence and severity of oral mucositis is influenced by the type of antineoplastic treatment administered and by patient-related factors
Conclusions

• We observed mucositis incidence in 125 patients
• Acupuncture seems to lower the mucositis incidence $\rightarrow$ less than 40% vs 60% (literature) of patients with oral lesions using reinforcing acupuncture points