

Original Research

**Acupuncture for Chemo-Related Nausea and Vomiting**Carmelo Guido <sup>1,\*</sup>, Valentina Selmi <sup>2</sup>, Cosimo Chelazzi <sup>2</sup>, Giulia Borsotti <sup>1</sup>, Rita Giachetti <sup>1</sup>, Vittorio Limatola <sup>1</sup>, Martina Sicurani <sup>1</sup>, Angelo Raffaele De Gaudio <sup>2</sup>

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doi:10.21926/obm.icm.1901020**Received:** September 29, 2018**Accepted:** March 19, 2019**Published:** March 28, 2019**Abstract**

**Background:** In recent years, complementary and alternative medicine (CAM) techniques have become very widespread; among these, acupuncture can play an important role in the treatment of adverse effects related to chemotherapy. This role has been recognized by the National Institutes of Health after many clinical studies, thus allowing the official introduction of acupuncture in supportive therapy for oncological diseases, particularly to prevent nausea and vomiting.

The aim of this paper is to describe the activity of the Unit of Integrated Medicine (UIM) of our tertiary hospital in relation to the prevention and treatment of nausea and vomiting associated with chemotherapy.

**Methods:** All patients cared for by the UIM are oncology patients undergoing chemotherapy, either alone or combined with radiotherapy or surgery. Each patient was examined before



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starting chemotherapy according to the principles of traditional Chinese medicine (TCM), particularly with a wrist and tongue test. The therapeutic protocol provided a weekly treatment with both somatopuncture and auriculopuncture for the whole duration of the treatment. The protocol included an assessment of nausea and vomiting using a numerical visual analogical scale (VAS) and a general assessment of quality of life (QOL) through standard questionnaires that were offered to patients before, during and at the end of the oncologic treatment.

**Results:** In the years 2017-2018, the UIM took care of 174 patients. The combination of acupuncture and auriculopuncture reduced significantly the duration and severity of CINV. Anyway some patients were not able to recognize the acupuncture as the cause of reduction of nausea. About QOL, most patients reported an improvement of their general QOL in the course of treatment, not only related to CINV, but also to a better control of other common problems such as pain/anxiety, dysgeusia or intestinal disorders.

**Conclusions:** In patients undergoing chemotherapy, acupuncture and auriculotherapy contributed to reduce nausea and vomiting and improve the general QOL.

### **Keywords**

Acupuncture; auriculotherapy; nausea; vomiting; chemotherapy

## **1. Introduction**

Anti-neoplastic chemotherapy is one of the pivotal treatments in the management of cancer patients as exclusive regimen or in association with surgery or radiotherapy. Its short- and long-term efficacies are also correlated to the compliance of patients to the treatment, thus strictly depending on patients' general conditions, comorbidities and side effects of therapy. Despite significant advances in the development of new molecules and optimization of modalities of administration, the side effects of chemotherapy may be cumbersome and can negatively influence the general QOL of the patients and the adherence to the therapeutic schemes, often leading to reductions of dose and frequency of treatments which can contribute to an impaired efficacy of chemotherapy itself; the side effects may be so important to induce patients to withdraw from the treatment or refuse it [1]. Nausea and vomiting are certainly the most common and the most burdensome for patients [2-4], and it is estimated that up to 75% of patients develop nausea and vomiting induced by chemotherapy (CINV) [5, 6]. This phenomenon can lead to serious complications such as dehydration, electrolyte abnormalities, malnutrition, lesions of the gastrointestinal mucosa, weight loss and psychological issues [7, 8]. The incidence and severity of the phenomenon depend on various factors including type of chemotherapy, poly-pharmacological protocols, dose, mode of administration and characteristics of the patient [9, 10].

The use of complementary and alternative medicine (CAM), particularly the acupuncture, is an extremely interesting therapeutic option that may reduce the incidence and severity of chemotherapy-related side effects and improve adherence of patients to therapeutic schemes; this may lead to an improvement of the general quality of life and contribute to the therapeutic success and better control of the underlying cancer disease [11-13].

In light of this, a Unit of Alternative Medicine (UIM) was created at the tertiary hospital “Azienda Ospedaliero-Universitaria di Careggi” (AOUC) in Florence, Italy, to implement a protocol to treat patients undergoing anti-cancer chemotherapy, alone or in association to surgery. To our knowledge, this is the first time that an Italian public tertiary care center implements a unit of alternative medicine as a mean to integrate care of oncology patients.

### **1.1 Purpose**

The aim of this paper is to describe the activity of the UIM at AOUC of Florence, Italy, in the prevention/treatment of CINV, including a narrative review of the scientific background underlying its clinical activity.

## **2. Materials and Methods**

All patients gave their written consent to the proposed treatment.

### **2.1 Setting**

Since 2007, there has been a Traditional Chinese Medicine (TCM) clinic at the AOUC. In 2017 the Unit of Integrated Medicine was created, which included the TCM, the new Acupuncture service and a phytotherapy office. The UIM is now part of the hospital Department of Oncological Anesthesia and Intensive Care, which takes on an integrated approach to care an integrated care for the oncological patients, both medical and surgical, ranging from perioperative care and anaesthesia, general/surgical intensive care unit, pain/palliative medicine and end-of-life care. The UIM is composed of 10 physicians, including 8 certified experts in TCM and acupuncture, and 2 phytotherapists, working on a 5/7 daily basis.

### **2.2 Patients**

The UIM takes care of cancer patients who are scheduled for chemotherapy, either alone or with radiotherapy, both prior/after oncological surgery (as adjuvant or neo-adjuvant treatment) or as an alternative to it (as palliative treatment). All patients referred to the UIM by the surgeon or oncologist are assessed before starting the first chemotherapy scheme or more frequently during therapies already initiated for the onset of nausea and vomiting refractory to traditional treatments.

The two main clinical goals at UIM are to treat cancer-associated pain and chemo-/radio-therapy related side effects, including, but not limited to CINV.

In this observational study, patients treated from January the 1st of 2017 to June the 30th of 2018 were examined treated? With regard to chemotherapy schemes, breast cancer patients were treated with cyclophosphamide and farmarubicin.

The protocol for head-neck cancer includes cisplatin (carboplatin if renal failure is present) and cetuximab in combination with fluorouracil if metastases are present.

All patients subjected to acupuncture also have standard pharmacological anti-nausea therapy consisting of ondansetron and dexamethasone before the chemotherapy session, and ondansetron or alizapride at home after the chemotherapy.

### 2.3 Therapeutic Protocol

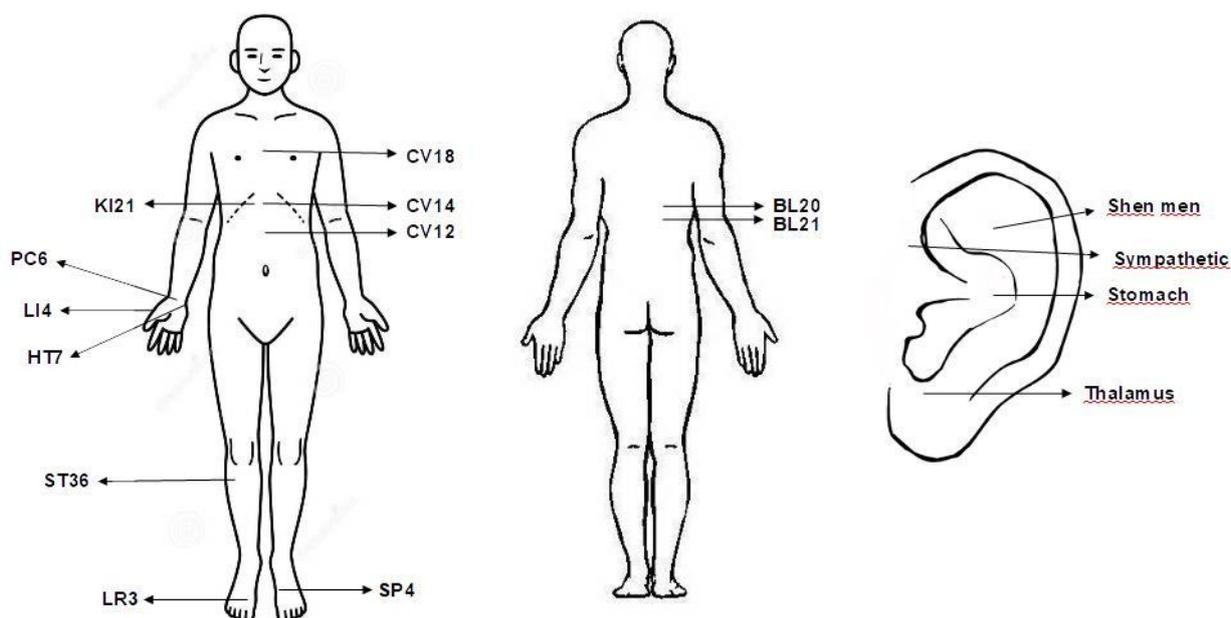
The therapeutic protocol for prevention and treatment of CINV includes both somatopuncture and auriculopuncture stimulation of surface points as indicated by TCM. Specifically, the points treated in somatopuncture are: HT7, PC6, CV14, KI21, CV18 (in manual toning or electrostimulation), CV12, SP4, ST36, LR3, BL20, BL21 and LI4 (Figure 1). On average, each patient undergoes a 30 minutes-session 1-3 times a week, depending on clinical status and response to therapy.

The auriculopuncture instead provides the stimulation of: Stomach, Shen Men, Cardia, Thalamus, and Sympathetic (neurovegetative) using vaccaria's seeds or pyonex needles (green 0.9 mm) (Figure 1). These treatments are performed the day before the chemotherapy session and after each session of somatopuncture; the needles or seeds are then removed after 48-72 hours by the patient itself at home.

Patients underwent acupuncture until the end of chemotherapy.

Acupuncture treatment is focused only on the symptom nausea and not on the underlying pathology; for this reason the type of treatment is the same for all patients.

No other TCM techniques have been used either because we are not personally experts and/or because in our experience for the treatment of nausea and vomiting, acupuncture is the most effective technique.



**Figure 1** Acupuncture and auriculopuncture points used.

### 2.4 Evaluation

During the first TCM consult, the examination of pulse and tongue are performed according to the principles of TCM. The severity of nausea and vomiting are evaluated at each session using a VAS scale (0 = absence of nausea, 10 = worst perceptible nausea); data were analyzed at the beginning, during and at the end of the cycle of acupuncture treatments.

The evaluation of overall adverse effects of chemotherapy is assessed using a quality of life (QOL) questionnaire, at the beginning, during and at the end of the cycle of acupuncture treatments; the QOL questionnaire was composed of questions inspired by the SF12 [14]. The QOL was expressed using a VAS scale (0 = best QOL, 10 = worst QOL).

### 2.5 Statistical Data Analysis

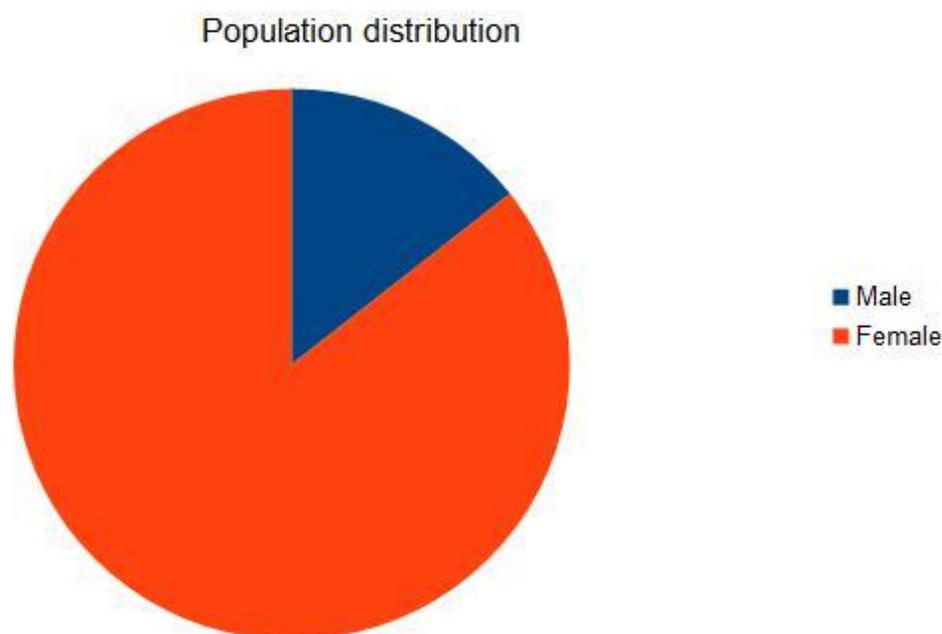
Data about nausea and QOL were presented as mean  $\pm$  SD. Statistical analyses of the data were conducted with a repeated measures ANOVA test followed by Tukey-Kramer Multiple Comparisons Test.

### 3. Results

From January the 1st of 2017 to June the 30th of 2018, the UIM cared for 174 patients (n = 94 in 2017, n = 80 2018) with a total of 2098 acupuncture sessions (n = 1200 in 2017, n = 898 in 2018).

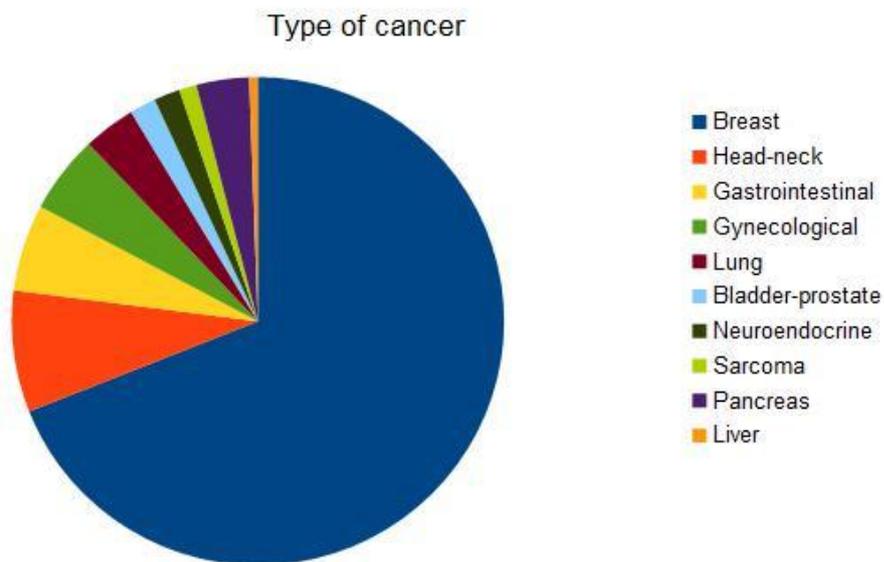
Patients' population was composed of 149 females and 25 males (Figure 2). The median age was 54.8 years (28-78) for women and 61.6 years (40-78) for men.

All patients had already started chemotherapy and went to the acupuncture clinic for nausea and vomiting that were refractory to traditional treatments.



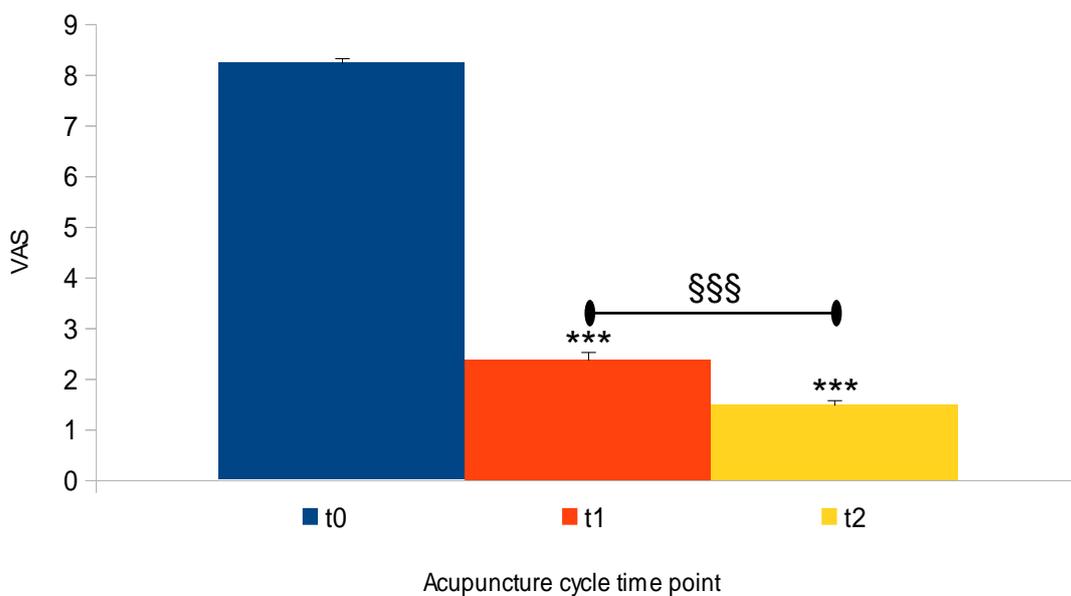
**Figure 2** The rates of women/men in the total population.

The most frequently treated cancer was breast (68.96%), followed by head-and-neck cancer (8.05%). The other treated cancers were mostly gastric, bronchial/lungs, uterine and ovarian, colon-rectal, pancreatic and lymphomas (Figure 3).



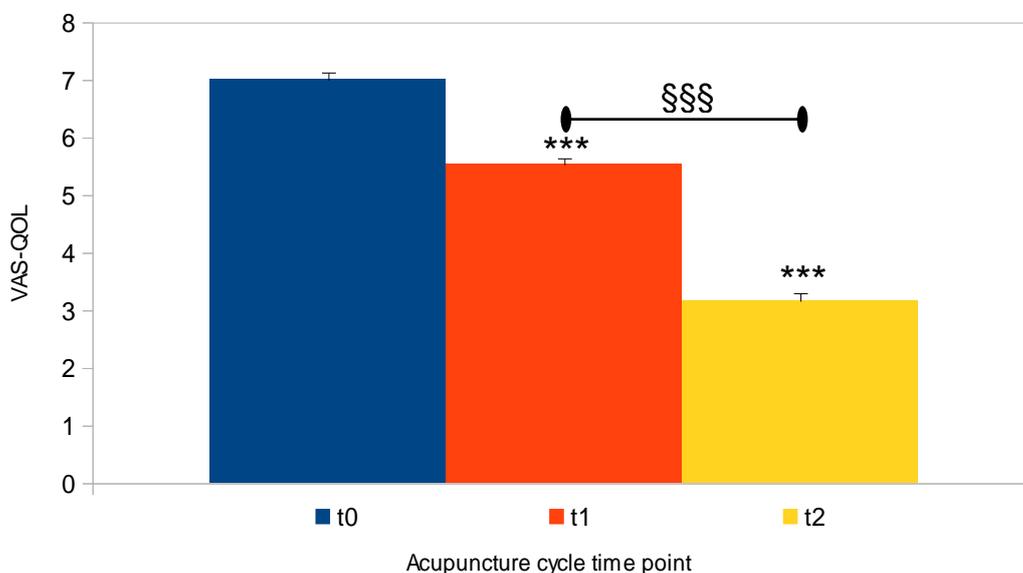
**Figure 3** The distribution of oncological disease in the total of considered patients.

Based on VAS analysis, the combination of acupuncture and auriculopuncture reduced significantly the duration and severity of CINV. The average nausea-related VAS went from  $8.23 \pm 0.10$  at the beginning of the cycle of acupuncture treatments (T0) to  $2.37 \pm 0.16$  at the half of the cycle (T1), and then to  $1.48 \pm 0.10$  at its end (T2) (Figure 4).



**Figure 4** Nausea evaluation. Acupuncture and auriculopuncture were associated with a significant reduction of nausea. \*\*\*  $p < 0.001$  T1 and T2 vs T0, §§§  $p < 0.001$  T2 vs T1.

As to the evaluation of QOL, 15 patients refused answering the questionnaire and were dropped from this analysis. The other 159 patients reported an improvement of their general QOL during the treatment, not only related to CINV, but also to a better control of other common problems such as pain/anxiety, dysgeusia or intestinal disorders. As an example, on T0 VAS=  $7 \pm 0.13$ , T1 VAS=  $5.53 \pm 0.11$  and T2 VAS=  $3.16 \pm 0.14$  (Figure 5).



**Figure 5** QOL evaluation. Acupuncture and auriculopuncture were associated with a significant improvement in QOL. \*\*\*  $p < 0.001$  T1 and T2 vs T0, §§§  $p < 0.001$  T2 vs T1.

Finally, 14 patients reported some acupuncture-related adverse effects. All of these were mild and transient, including pain, small haematoma or bleeding at the needle’s site of insertion; no other major complications were noted.

#### 4. Discussion

In our experience at the UIM, the use of somatic and auricular acupuncture was associated to a reduction in incidence/duration and severity of CINV and to an increase in general QOL of various cancer patients undergoing chemotherapy. The present study confirmed a previous paper showing, in cancer patients, a decrease of 63.6% in mean symptom intensity after acupuncture treatment. In fact, a study performed in cancer patients showed a decrease of 63.6% in mean symptom intensity after acupuncture treatment) [12].

In literature, the term “CINV” includes 4 different conditions based on the timing of administration of chemotherapy: acute/delayed/anticipatory/refractory; each one with typical characteristics and consequently associated with a specific prophylactic and therapeutic procedure [13].

To date, the standard treatment of CINV involves the combination of anti-serotonergic agents (e.g., ondansetron, granisetron or tropisetron) with steroids [15]. While the use of single agents works in 40-70% of cases for acute CINV, their association is efficacious in 80-90% of patients [16]. However, some patients still do not respond; moreover, the infusion of those agents is performed

during the infusion of chemotherapy and does not prevent nor treat the late CINV. Some, not negligible, secondary effects need also to be considered, e.g. headache, constipation, insomnia or vertigo [17, 18].

In this context, the use of techniques of complementary and alternative medicine (CAM) is an extremely interesting therapeutic option.

Numerous studies show that the use of CAM is widespread in the Western countries and some observational studies in the 1990s have found that the use of CAM is more common among cancer patients than those suffering from other diseases. In Europe, it has been estimated that 15-73% of cancer patients are cared for with some kind of CAM with an average of about 36% [19, 20]. In France, 34% of cancer patients were treated with a complementary therapy [21]; in Germany, 59% of patients undergoing radiotherapy, especially women with breast cancer, uterine-ovarian, kidney, rectum and Hodgkin's lymphoma [22]. A survey conducted in 7 European countries on patients with colorectal cancer found that 32% had been treated with CAM after diagnosis [19]. The study reports a high level of satisfaction with these therapies intended, above all, to enhance the body's ability to fight the disease and improve the state of psycho-physical well-being (the general "fitness" of the patient). In the United States, the use of CAM among cancer patients was estimated between 42-83% and the specific use of acupuncture between 1.7-31% [23]. A study conducted on 2,562 women (aged 28-74 years) with breast cancer described a 50% use of CAMs [24].

Against this widespread diffusion among patients, sharing of this therapeutic option with one's own physician is scarce: only 24% of those who use a form of CAM during oncological disease refer to their doctor [25] and, according to a study conducted in the USA on breast cancer, up to 92% do not speak with their oncologist about the use of CAM [26].

The characteristics of the patients using CAM are also peculiar. It is mainly women affected by cancer, with a good level of education and a more self-conscious approach to their health [27]. According to Nahin et al., 60-70% of women with breast cancer (compared to 50% of women with other type of cancer) use some kind of CAM [28].

According to some authors, compliance with complementary treatments (e.g. acupuncture) may be influenced by various factors such as access to treatments, patient characteristics (demographic, sociocultural) and pathology (cancer type, presence of metastases, type of treatment) [24, 27-29].

In our experience, we did not find a substantial difference in adherence to the acupuncture protocol, both in relation to sex, and in relation to the type of pathology, probably because the selection of patients really motivated is carried out by colleagues' oncologists and / or radiotherapists at the time of interview.

CAM is considered a chance to alleviate the symptoms of the disease and to reduce the burden of the adverse effects of anti-cancer therapies and to improve QOL of patients, their fitness and their compliance to therapies.

Consistently, numerous clinical trials have evidenced the role of acupuncture for some of the side effects of chemotherapy (post-surgical pain; flushing, fatigue); the most convincing results are related to the CINV. Many studies [29, 30] involve women with breast cancer undergoing chemotherapy and anti-emetic therapy, to which acupuncture has been added in various forms. There are also numerous evidence of efficacy of acupuncture for post-surgical and post-radiotherapy nausea and vomiting [31].

Based on these and many other evidence, the World Health Organization (WHO) has recognized a number of conditions that could benefit from acupuncture, including nausea and vomiting induced by chemotherapy, pain, alcoholism and other substances addiction, asthma and COPD. In addition, the Food and Drug Administration in 1999 removed acupuncture from the category of "experimental therapies", to consider it and regulate it as other validated medical therapies [32].

Despite all of this, many physicians remain skeptical about acupuncture. There are many factors that contribute to this, including the fact that its scientific basis remains unclear; that it is based on some philosophical aspects difficult to understand for the modern, Western society; the technical language may sound "exotic" and unusual for a Western mind; and the traditional Chinese system does not correspond to the anatomical and neurological concepts of Western medicine. Furthermore, acupuncture is often seen more as an art than as a science because there are many factors that can influence the results of the therapy [33, 34].

The acupuncture, both somatic and auricular, is a technique belonging to CAM and TCM. It has been widely accepted and recognized as an effective co-treatment of several chronic diseases such as cancer [35]. Specifically, it has been officially recognized as a possible therapy for CINV [36].

The pathophysiological mechanism by which acupuncture can modulate CINV is not yet fully understood. Probably, the signal generated by the stimulation of muscular nerve endings is transmitted to the brain where it induces the release of neurotransmitters, cytokines and hormones. Indeed, every acupoint on the body surface has a specific effect, a specific therapeutic indication and not simply due to the release of mediators and cytokines [36].

As described above, our protocol is composed by pericardium 6 (P6 or Neiguan), stomach 36 (ST36 - Zusanli) and vasoconception 12 (CV12 - Zhongwan) specifically aiming to reduce nausea and vomiting [36, 37]. Among these, P6 is certainly the most used for the prevention and treatment of nausea and vomiting. It can be stimulated using various techniques such as manual acupuncture, electroacupuncture and acupressure [36, 38].

In our experience, stimulation of P6 together with other acupoints has allowed a good control of nausea and vomiting, similar to what is described in (the) literature.

Moreover, the stimulation of P6 is also related to an anxiolytic effect. This action was investigated using f-RMN techniques that showed, following P6 stimulation, an increase in the signal at the cerebellum, insula and hypothalamus level, thus recognizing a physiological explanation of its anxiolytic effect [39].

The reduction of anxiety is probably one of the factors that, together with a good control of nausea and vomiting, are responsible for a high percentage of patients who report a satisfactory improvement in QOL.

Auricular therapy, often associated with somatopuncture in the treatment of CINV, allows enhancing and prolonging the positive effects of treatment on nausea and vomiting. Auriculotherapy is recognized by WHO as a form of micro-acupuncture that can act on the whole body (163). The WHO has also established a map of the headset system with standardized nomenclature (163). This system includes auricular anatomy and demonstrates evidence of therapeutic efficacy and has been accepted internationally [40].

According to TCM, the areas on the auricle that we used to treat CINV are: "sympathetic" (point 44): under the fold of the helix, at the beginning of the lower branch of the Y of the antelice;

"Stomach" (point 72): where the root of the helix ends; "Shen men" (point 48): point of the triangular dimple; "Occipital" (point 25): upper posterior angle of the antitragus.

The point "stomach" (72) is related in its physiology to the points (81) pancreas and (83) spleen and governs all the digestion, not only the physical but also the spiritual ones (education, ideas, experiences). Its stimulation is indicated in all of the diseases of the digestive tract and in some diseases of the central nervous system, including motion sickness and insomnia.

The "shen men" (48) is also called "door of destiny", according to the Chinese name. It has psychosomatic activity. It is indicated as a sedative in general, in anxieties and for intoxication. "Occipite" (25) is indicated in thalamic syndromes and cerebellar pathologies. It also acts in the case of motion sickness. The "sympathetic" (44) is indicated in neurovegetative syndromes, in tachycardia, and in abdominal colic. It is an important point for thoraco-abdominal anesthesia.

An increased endogenous release of opioids may play a role, as shown by studies on analgesia induced by auriculotherapy [41, 42].

Another possible mechanism is the parasympathetic modulation induced by the stimulation of the areas innervated by the vagus nerve. In a study conducted in 2008 on rats, it was seen that the manual and electrical stimulation of needles at the level of the helix and of the hollow caused an increase in intra-gastric pressure and the contractility of the stomach, with a decrease in heart rate [43].

However, the studies conducted on auriculotherapy and the prevention of CINV and PONV are limited in number to date.

There are a number of limitations of this study. First, although we have achieved good retention and patient compliance with acupuncture treatment, we had difficulty in recruiting patients before starting chemotherapy. The main reason is that patients decide to undergo acupuncture only when the chemotherapy-induced nausea does not respond to standard therapies. It would probably require a campaign to sensitize doctors (surgeons and / or oncologists).

Secondly, the study would be enhanced by a case-control group of similar patients as a comparison arm. This is an observational study aimed at obtaining preliminary data for a subsequent randomized case-control study. Without these data, the ethics committee of our hospital would not approve a case control study.

Third, it could be interesting to recruit and compare patients based on the number of cycles of chemotherapy.

Finally, the use of a more detailed tool to assess the quality of life (for example questionnaire SF36) could give more complete and precise information.

## **5. Conclusions**

In our clinical experience, as described in the literature, somatic acupuncture and auriculotherapy seems to be an effective integrative treatment for the prevention and treatment of chemotherapy-induced nausea and vomiting. Further studies are needed to evaluate the magnitude of the clinical evidence of the phenomenon.

## Author Contributions

Carmelo Guido designed the protocols of treatment at the UIM and treated patients; he contributed to data collections and drafted the manuscript. Valentina Selmi and Cosimo Chelazzi performed the analysis of data and reviewed the manuscript. Giulia Borsotti, Rita Giachetti, Vittorio Limatola, Martina Sicurani treated patients at the UIM of the AOU-Careggi and collected the data. Raffaele De Gaudio contributed to design the protocol and supervised the collection of data and the drafting of manuscript.

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## Competing Interests

The authors have declared that no competing interests exist.

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