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Research paper

Feasibility of a trial with Tibetan Singing Bowls, and suggested benefits in metastatic cancer patients. A pilot study in an Italian Oncology Unit

Livia Bidin^{a,*}, Luca Pigaiani^c, Manlio Casini^c, Pietro Seghini^b, Luigi Cavanna^a

- ^a Oncology Unit, Oncology-Haemathology Department, Ospedale Civile "Guglielmo da Saliceto", Piacenza, Italy
- ^b Epidemiology and Risk Comunication Unit, Ospedale Civile "Guglielmo da Saliceto", Piacenza, Italy
- ^c Scuola Olistica Ananda Ashram, Milan, Italy

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ABSTRACT

Introduction: Sound is a physical pervasive phenomenon inducing resonance influencing cell metabolism with bodily water mediating the effects of vibration. Tibetan Singing Bowls may induce state of wellbeing in patients with cancer which can be measured.

Methods: This pilot study included 12 metastatic cancer patients undergoing 6 sessions using Tibetan Bowls. Objective (electrocardiography, skin conductance and electroencephalography) and subjective measurements (QoL, Anxiety/Depression, Distress, Fatigue) were performed. End points were feasibility (recruitment, attendance, compliance to treatment) and benefits (amelioration in QoL, anxiety, distress, arousal and mental exhaustion).

Results: All 12 patients were recruited over a two-week period; 83% attended all sessions. 83% of the patients completed questionnaires to assess subjective efficacy. 59 instrumental tests were performed out of 60 sessions completed. For subjective parameters, a statistically significant difference emerged only for the Distress Thermometer (2.4 vs 5.3 p=0.0005). Objective parameters: 1) tonic skin conductance level (SCL) decreased significantly (p=0.0091) and phasic SCL (p=0.0064); 2) heart rate variability (HRV) significantly increased (p=0.0041); 3) EEG registration in anterior-frontal areas revealed changes in beta, alpha and inter-hemispheric coherence, (beta: p=0.09; alpha p=0.046; coherence p=0.084).

Conclusion: The feasibility endpoints (acceptance, attendance and compliance) were achieved; personalized programs should be offered to patients at risk of rapid worsening conditions and to subjects affected by bone metastases. A visual tool for subjective distress appears more appropriate than validated questionnaires. Useful tools for collection of objective data are SCL, HRV, and anterio-frontal EEG. Tibetan Bowls decrease anxiety, arousal, involuntary mental activity and stress. Larger trials should confirm these results.

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1. Introduction

From ancient times, some important effects have been attributed to the interaction of sound with living systems; in fact, particular instruments were developed to accompany meditation, religious rituals and social ceremonies, in which sound was used to align minds and souls and to create a pervasive coherence of the whole community during solemn festivities [1,2].

In the human body, sound – a physical vibrational phenomenon inducing resonance – passes through hearing and non-hearing

E-mail addresses: liviabidin@gmail.com, l.bidin@ausl.pc.it (L. Bidin), luca.pigaiani@gmail.com (L. Pigaiani), massaggiosonoro@gmail.com (M. Casini), p.seghini@ausl.pc.it (P. Seghini), l.cavanna@ausl.pc.it (L. Cavanna).

http://dx.doi.org/10.1016/j.eujim.2016.06.003 1876-3820/© 2016 Published by Elsevier GmbH. tissues. "Sound Massage" is a term that emphasizes the perception of the vibration by the whole organism. Notably, "Sound Therapy" differs from "Music Therapy"; "sound" is an audible vibration, while "music" is as an artificial product, made up of sounds, that consists of harmony, melody and rhythm [3]. "Sound Therapy" uses sound as a physical phenomenon, with neither rhythm nor melody, to create the optimal resonance between the vibrations of the singing bells and the vibrations of the specific receiver. Sound therapists abstain from melodic structures that could recall previous experiences. Gongs and Tibetan Singing Bowls are traditional instruments used in sound therapy. The resonance of their vibrations with the body of the receiver dictates the optimal modality of sound treatment [4,5].

The physics of Singing Bowls and Gongs have been reported in various papers [6-11]. Resonance is defined as a phenomenon in

^{*} Corresponding author.

L. Bidin et al./European Journal of Integrative Medicine xxx (2016) xxx-xxx

which an oscillating system can absorb energy from an external source, with particular efficiency at only one specific frequency. Every physical system – characterized by its own frequencies of oscillation – can enter into resonance with an external source.

A few years ago, a team of biologists amplified and studied sound waves produced by cells; the sound of the cells seems to be related to cell metabolism and to specific gene expressions; distinct vibrations, which join cell surface via the cytoskeleton, seem to be the result of specific DNA assembly and disassembly. This could imply that external vibrations play a role on the modulation of cell activity [12].

Bio-resonance indicates the effects of the sound on human body. It arises at two levels: a mechanical-acoustic level, due to the pressure wave of the sound on every tissue of the body; and an electro-magnetic level, due to the ultra-weak electro-magnetic field created by every sound, affecting bodily water, molecules and cerebral waves.

From the first experiences with Tibetan Singing Bowls in cancer patients, we noticed that they experienced a profound relaxation, a reduction in anxiety and a state of well-being, expressed in various metaphors and analogies; for example, patients said, "I felt the sound of the singing bowls joining and melting together and I sensed a breeze that wiped out anxiety and pain"; "I could talk with myself again"; "I had the perception of my body and this helped me not to be afraid"; "I felt that I could again trust in my self-defence ability". As a result, patients regained awareness of their bodies, a higher mood and a good disposition towards the future. Patients said that their subjective well-being, difficult to express, lasted up to three days after a session [13].

2. Materials and methods

We conducted a pilot study to evaluate the feasibility of a trial with Tibetan singing bowls in the clinical setting of an Oncology Unit. We underline that, as a "pilot study", this is a small scale study specifically designed in order to evaluate feasibility, drawbacks, tools/methods of measurements and effects, prior to perform a full scale research project. Consequently we included only 12 metastatic cancer patients, and defined as primary end points recruitment, attendance, and compliance (feasibility). We considered the amelioration in subjective and objective parameters as secondary endpoints, because we wanted to recognize possible suggestions regarding the potential benefits of singing bowls on metastatic cancer patients, conscious of the limited significance of the results due to the small sample size. Hospital ethics committee stated that a formal approval was unnecessary for this study, due to the lack of invasive interventions nor drugs administrations to the patients, but nevertheless patients received written information about the procedure and signed their informed consent.

Twelve consecutive out-patients were included in this pilot study, conducted in a general hospital in northern Italy; a first group of six patients was recruited in October 2014 and the last six in March 2015. Inclusion criteria were defined as follows: metastatic cancer patients, ECOG PS 0,1,2, willing to attend all six sessions and to undergo all tests and questionnaires, with written informed consent. Study sessions extended from November 2014 to June 2015.

Treatment was carried out according to the method of Sound Therapy called "Metodo Bagno Armonico®" [5], patients were subjected only to vibrations deriving from the sweet percussion of the bells, with no verbal intervention nor hint of the researchers aiming to direct the relaxation. According to a Portuguese study [10] we used handmade "asymmetrical" bowls, able to produce the most audible and stable harmonics which can enter in resonance with the body; we used percussion of the bowls for the higher ability to produce audible harmonics than rubbing. Bowls used in the "Metodo Bagno Armonico®" [5] consists of 3 bowls 14–16 cm, one bowl 23–26 cm and one bowl 28–32 cm in diameter. All of the bowls are characterized by the presence of 6–8 harmonics audible at high, median and low frequencies; 'prevalent frequencies' are dependent on the diameter of the bowl. Over a 3 months interval, each patient underwent 6 individual sessions of a 1h treatment with Tibetan bowls. In the on-site sessions, instruments were mainly Tibetan singing bowls. Other ancillary instruments were Feng Gong, Tingsha and Wind Chimes. During the treatment, the patient was lying down on a Japanese straw mat (tatami) or on a massage bed. Placed on specific points of the receiver's body, Tibetan Bells were played by percussion.

We collected subjective measurements before the first and before the last session, and objective data before and after each session.

To define the primary end-point – "feasibility" – we measured recruitment, attendance, compliance, and, to verify the secondary end point – "efficacy" – we measured subjective and objective parameters.

Subjective measurements included validated questionnaires for: Distress (**DT**, *Distress Thermometer* and **PDI**, *Psychological Distress Inventory*), Anxiety/Depression (**HADS**, *Hospital Anxiety and Depression Scale*), Fatigue (**Facit-F** *Fatigue Scale*) and Quality of Life (**SF-36**, *Short Form-36 vitality scale*) (Table 1).

Objective measurements included: Alert/arousal indicators (Tonic Skin Conductance, Heart Rate, Breath Rate); an Indicator of the "Autonomic Adaptability" (Heart Rate Variability); Indicators of "Mindfulness", a mental state of thoughtful awareness (EEG pattern, phasic Skin Conductance) [14–27].

The following Instruments were used for objective measurements and statistical analysis:

Cutaneous conductance (SCL)—microsiemens (μ S): Mind Lab Set, software MindScan & Pscychofeedback; Setting: sitting, open eyes, 3 min pre, 3 min post.

RHR (bpm), **Oxyigenation** (SpO2%) **and breath rhythm** (bpm): Tinké (bluetooth for Android), software app Tinké; Setting: sitting, open eyes, 1 min pre, 1 min post.

Table 1 Tests and domains assessed.

TEST	DOMAIN
SF-36 Medical Outcomes Study Short Form-36	a generic QOL instrument assessing several distinct domains. The standardized mental component summary (MCS) and physical component summary (PCS) scores are presented, with higher scores denoting better OOL.
DT Distress Thermometer; general distress	The Distress Thermometer significant distress is indicated by scores exceeding the cutoff (≥4). (Jacobsen et al., 2005). (DT ; Roth et al., 1998) assessed general distress;
PDI Psychological Distress Inventory	PDI measures the impact of the illness and the treatments in psychological distress in cancer patients. (G Morasso et al. Oncology 1996;53:295-302)
HADS anxiety/depression sub-scales of the Hospital Anxiety and Depression Scale	Patients also completed the Hospital Anxiety and Depression Scale (HADS-A; Zigmond & Snaith, 1983).
FACIT-F Functional Assessment of Chronic Illness Therapy Fatigue subscale	The Functional Assessment of Chronic Illness Therapy Fatigue subscale (FACIT-F; Yellen, Cella, Webster, Blendowski, & Kaplan, 1997) assessed fatigue during the past 7 days.

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