kairos

Osteopatia e Medicine Integrate

PEDIATRIC OSTEOPATHY

Experience in hospital clinics and specialist training

in collaboration with

SIOP

ITALIAN SCHOOL OF PEDIATRIC OSTEOPATHY

Meyer

PEDIATRIC HOSPITAL OF FLORENCE

kairospecial

Presentation of the project at Pristina Hospital

What is osteopathy ?

Osteopathy is a health profession recognized by the WHO with exclusively manual diagnosis to management and treatment of patients. It is an approach based on supporting the patient's health, using different types of techniques:

- Articulatory, Visceral, Lymphatic, Craniosacral, Muscle energy, Myofascial release or directed to soft tissues. The osteopath collaborates with all medical and health professionals:

- Orthopedists, Physiatrists, Neurosurgeons, Ophthalmologists, Dentists, Gynecologists, Otolaryngologists, Pediatricians, Physiotherapists.
The multidisciplinary approach between osteopaths and medical specialists integrates and improves the diagnostic framework and the therapeutic process for the benefit of the patient.
Through manipulative treatment, the Osteopath stimulates the restoration of physiological mobility at the level of the various systems which, through synergistic and coordinated activity, regulate the normal functioning of the body.

What is Pediatric Osteopathy?

In the Osteopathic field, the approach to the Child requires awareness and additional skills, the Pediatric Osteopath does not focus on the disease, but seeks Health through the activation of self-regulation mechanisms, which in the child are extraordinarily active, this is allowed by the SNA's ability to regulate the health status of the Child.

Pediatric Osteopathy in the Hospital: experience at Meyer Children Hospital in Florence

Pediatric Osteopathy begins to give its support to hospitalized children at the Meyer Hospital in Florence in the spring of 2008, with the meeting of the Osteopath ***Tommaso Ferroni*** and Doctor ***Lorenzo Genitori***, primary of Neurosurgery.

Since then, the presence of Osteopathy in the hospital has grown significantly, both as a collaboration in the various departments, and with the various medical-scientific studies carried out.

Scientific Research

The first medical-scientific study was called "Osteopathic Approach in a Department of Neurosurgery".

The research work, carried out from 2009 to 2011, was based on the evaluation of the benefits of osteopathic treatment on children hospitalized in the neurosurgery department, divided according to the pathologies, referring in particular to the reduction of post-operative or post-traumatic pain.

The study led to excellent results which were exhibited in the context of the International Congress of Osteopathy "Towards an integration between medicines" held in Florence in 2011.
In the following years, the evaluation study of the efficacy of Osteopathic Manipulative Treatment * (OMT*) in pediatric patients after surgery related to Neurosurgery has always been carried out through the evaluation of post-operative pain, pharmacological load, hospitalization times, the quality of life and school recovery.
The observational study lasted 4 years. The results demonstrated the effective reduction in pain of the treated children, thanks to daily tests by nurses. Furthermore, a decrease in the use of drugs and hospital stays was found. Thanks to subsequent phone calls, it was also possible to observe a rapid recovery in school activities and therefore in quality of life.
The observation of the benefits of BMT through the Outcomes studied confirms the support of the hypotheses of this study and favors new ones, such as the possibility of implementing the post-surgical management protocols of the child, with the administration of BMT in supporting the physiology, both in acute and subacute phase. The study was published in the monthly information magazine Toscana Medica, edited by the Medical Association of Florence.

The research dedicated to the impact of osteopathic manipulative treatment in patients suffering from Thalassemia Major, treated at the Meyer Oncohaematological DH service, was also published in the journal HSOA Journal of Community Medicine and Public Health Care.

The study dedicated to the evaluation of perceived pain and questionnaire on the quality of life in children undergoing appendectomy is currently being published.

The Pediatric Osteopathy Outpatient Clinic

Thanks to the ever wider collaboration with the various departments of the AOU Meyer, Osteopathic Manipulative Treatments have been increasingly requested by doctors and patients. After the first studies, the regional code of Complementary Medicine was created, which allowed the opening in 2011 of the first, and still unique in Italy, Osteopathy Clinic under a convention, open to residents of the Tuscany Region from 0 to 18 years.

Over the years, the Pediatric Osteopathy Clinic within the Meyer has obtained significant data in terms of treatments performed. From 2011 to 2021 there is an ever-increasing demand, which has created the need

to expand opening hours and bookable slots. After 10 years of activity, there are more than 6,500 treatments performed on a number of about 1,800 patients.

Other collaborations with hospitals

A collaboration with OPA - Heart Hospital of Massa-Carrara (Tuscany) has been active since 2021, an international center of excellence for cardiology and cardiac surgery services for neonatal, pediatric and adult patients. Our osteopaths carry out treatments to hospitalized patients in collaboration with doctors, carrying out a scientific study currently underway.
Our team also collaborates with the neonatal intensive care department of the Santa Chiara hospital in Pisa.

The Italian School of Pediatric Osteopathy - SIOP

The Italian School of Pediatric Osteopathy was created in October 2015. The school is directed and managed by Dr. Tommaso Ferroni. There are three-year educational program dedicated to the training of Osteopaths already in possession of a diploma, who wish to dedicate themselves to supporting the health of children.

Each class is composed of about 30 students who during the year, in addition to theoretical seminars dedicated to a broad Medical-urgical and Osteopathic education, have the opportunity to gain experience with practical clinics within various hospitals such as the “AOU Meyer” and the Neonatal Intensive Care of the Santa Chiara hospital in Pisa.

Kairos Osteopathy and Integrated Medicine Cultural Association

Kairos Osteopathy and Integrated Medicine Association's mission is to support health through osteopathy, especially pediatric osteopathy, through volunteer projects, training of professionals and international collaborations.

One of the projects is Kairospecial, a Childhood Neuropsychiatry Clinic where children and young people with neuropsychiatric disorders are treated in various cities in Italy and abroad (we also have an office in Spain) every first saturday of the month by a team of pediatric osteopaths directed by Dr. Tommaso Ferroni.

The collaboration between Italian School of Pediatric Osteopathy , Kairos Osteopathy Association and the project in Kosovo

Kairos Osteopathy and Integrated Medicine Association offers Pediatric Osteopaths trained at the "Italian School of Pediatric Osteopathy" with the purpose to provide care to children hospitalized in the University Hospital of Pristina in Kosovo, directly on site.

The different teams, formed each time by a tutor and three students, will be available at the hospital on two monthly basis.
The 4 operators present will treat the hospitalized children in collaboration with the doctors. Data collection and osteopathic evaluation forms will be created with particular attention to perceived pain, hospitalization time, pharmacological load, quality of life. The project will result in a medical-scientific study followed by the SIOP and Kairos Organizational Secretariat, to assess the impact of osteopathic treatments on children.
The project can provide for the training of local osteopaths through theoretical lessons and practical training both on the territory of Kosovo and in Italy in the city of Florence, ensuring that over time the local osteopaths can treat children in their nation.

Contacts

Italian School of Pediatric Osteopathy srl
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Scientific Director: Dr. Lorenzo Genitori

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Website: www.siop-fi.it
Email: info@scuolaosteopatiapediatrica.it

Kairos Osteopatia e Medicine Integrate

www.kairos-osteopatia.it - info@kairos-osteopatia.it
Headquarters: Via Massei 2 , Lido di Camaiore 55041 Italy

The collaboration with the Meyer Pediatric Hospital of Florence

Since 2009 Dr. Tommaso Ferroni has been present in the hospital as an osteopath for the treatments of children hospitalized in the Neurosurgery department.

Since 2011, opening of the first Pediatric Osteopathy Clinic under an agreement with the Tuscany Region within the hospital: children access through the hospital with a reduced payment or exemption. The pediatric osteopaths, coordinated by Dr. Ferroni, treat in all departments of the Meyer Hospital called, through the opening of consultations, by the doctors of the department itself. The children who benefit from osteopathic treatments in hospital, therefore, are both hospitalized patients (internal) and children who access the osteopathy clinic (external).

Over the years, several medical-scientific studies have been carried out and published. We report the study relating to the evaluation of the effectiveness of Osteopathic Manipulative Treatment (OMT) in post-surgical pediatric patients relating to Neurosurgery, through the evaluation of post-operative pain, pharmacological load, hospitalization times and quality of life and school recovery. The study was published in “Toscana Medica” in April 2022.

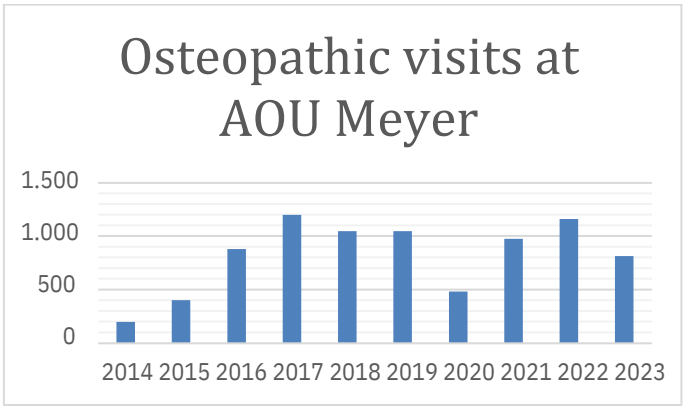
Furthermore, the research dedicated to the impact of osteopathic manipulative treatment in patients suffering from Thalassemia Major, treated at Meyer's DH Oncohaematology service, was recently published in the "HSOA Journal of Community Medicine and Public Health Care" of the US publishing house Herald Scholarly Open Access. The study dedicated to the evaluation of perceived pain and questionnaire on the quality of life in children undergoing appendectomy is currently being published.

Over the years, the Pediatric Osteopathy Clinic within Meyer has obtained significant data in terms of treatments carried out. From 2011 to 2023 there is an ever-increasing demand, which has created the need to expand the opening hours and bookable slots. After 12 years of activity, there have been **more than**

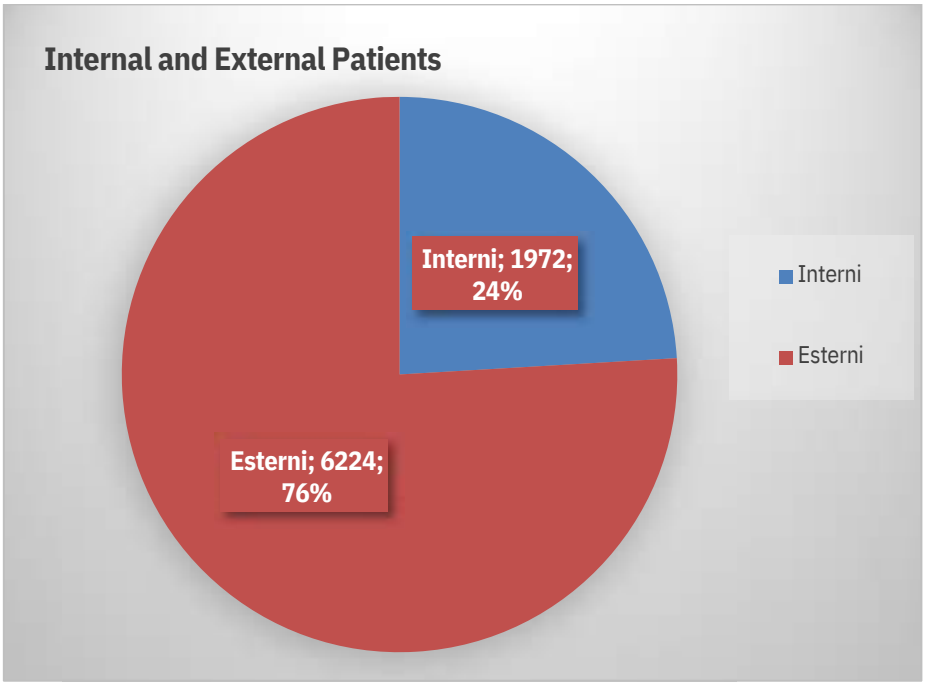
8,000
manipulative treatments carried out.

OSTEOPATHIC TREATMENTS CARRIED OUT FROM 2014 TO SEPTEMBER 2023 AT AOU MEYER

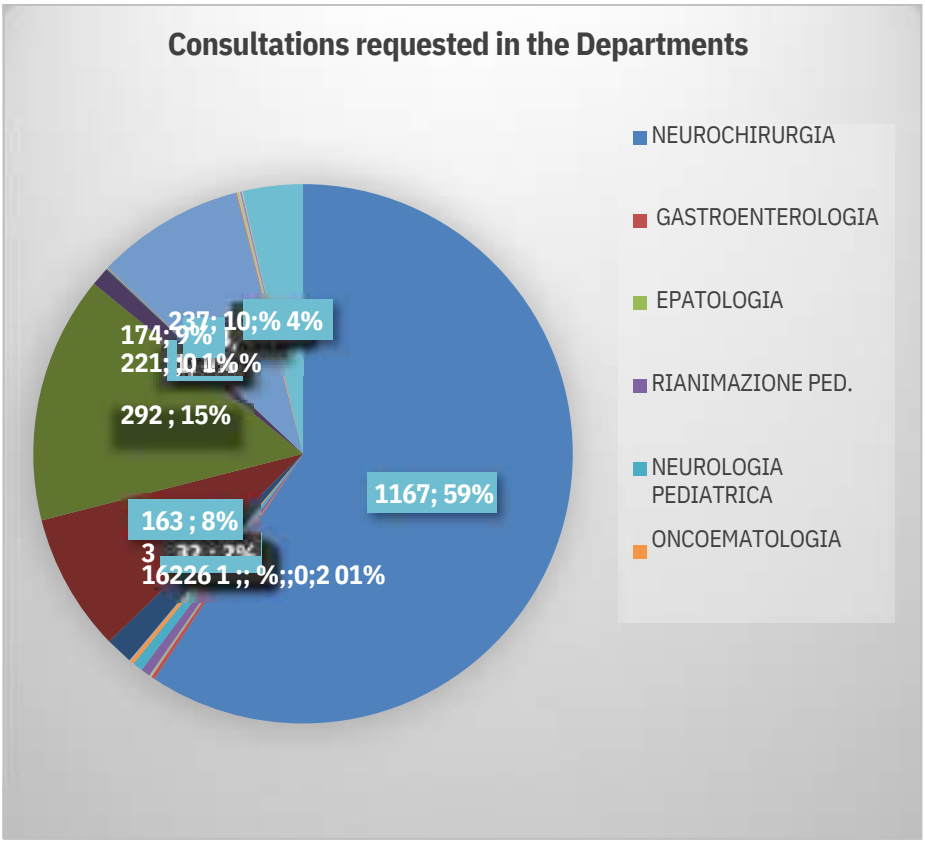
Year	Osteopathic visits at AOU Meyer
2014	198
2015	401
2016	878
2017	1.198
2018	1.047
2019	1.047
2020	480
2021	974
2022	1.161
2023	812
TOT	8.196



PERCENTAGE OF INTERNAL AND EXTERNAL PATIENTS WHO HAVE USED OMT AT AOU MEYER



REQUESTED ORIGINS CONSULTING FOR INTERNAL PATIENTS



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Osteopatia e Medicine Integrazte

SIOP

SCUOLA ITALIANA DI OSTEOPATIA PEDIATRICA

PEDIATRIC OSTEOPATHY IN KOSOVO

Sheikha Fatima Children's Hospital - Pristina

The Pediatric Osteopaths of the Kairos Association in Kosovo: for the first time Osteopathy is formally authorized by the Ministry of Health of the Republic of Kosovo

Meyer

From the experience and studies carried out at the AOU Meyer in Florence, the project was born at the pediatric hospital in Pristina

kairos-osteopatia.it info@kairos-osteopatia.it +393894831701

Synthesis:

The project of the Kairos Osteopathy and Integrated Medicine Association in Kosovo is based on the dissemination of knowledge relating to Pediatric Osteopathy throughout the national territory, through collaboration with the Kosovar Ministry of Health and, in particular, the periodic presence of osteopaths trained at the Italian School of Pediatric Osteopathy within the Sheikha Fatima Children's Hospital in Pristina, the only pediatric hospital in the nation.

The objective is to support the health of children hospitalized in each department. As per a study carried out at the AOU Meyer in Florence in the Neurosurgery department, osteopathic treatment can be effective in reducing pain, pharmacological load and hospitalization times. Furthermore, during each mission a day will be dedicated to children who have already been discharged, who can return for osteopathic treatments, or other children with disabilities, traumas or particular dysfunctions.

Future objectives are based on increasing missions every year with a greater number of osteopaths present, in order to carry out more treatments and cover the entire hospital.

In addition to this, the association will look for ways to start training local doctors through international cooperation between Italian and Kosovar healthcare professionals.

Introduction: from the project to the first Exploratory Mission

The Pediatric Osteopathy project in Kosovo was born several years ago, from the idea of offering osteopathic treatments to children hospitalized in the Onco-Hematology department at the Children's Hospital in Pristina. The first exploratory mission was carried out by Tommaso Ferroni in February 2023, on the occasion of a trip by an Italian delegation of doctors and representatives of Tuscan associations for the implantation of some pediatric venous catheters. The interest was immediately very high and the chief of Oncology gave the possibility of treating the children in the oncohematology department, as well as organizing a conference in the presence of all the department heads of the hospital to explain the osteopathic rationale, especially in reference to the decrease of patients' pain, as per a medical-scientific study carried out at the AOU Meyer in Florence and recently published*.

*attached study - *Toscana Medica*

The official license of the Kosovar Ministry of Health and the second Mission

In the following months, thanks to diplomatic work between the Kairos Osteopathy and Integrated Medicine Association, the Management of the Children's Hospital of Pristina and the Kosovar Ministry of Health, an official national license was drawn up for the group of osteopaths coordinated by Tommaso Ferroni, recognized as healthcare professionals authorized to treat children within all departments of the hospital.

This led to the second Kairos mission to Kosovo in November 2023, with the presence of a team of 4 osteopaths and a team manager for 4 days. During the mission, all the children present in the onco-hematology department were treated for 3 days in a row, noting the data and pathologies present and any differences and perceptions during the OMT.

Furthermore, the team was present in other departments of the hospital, particularly in the pediatric intensive care unit and in the neonatal intensive care unit, establishing contacts with the heads of the departments.

Kadrije Sherifi

Kryesuese e BLPSH

Republika e Kosovës

Republika Kosova-Republic of Kosovo

Qeveria-Vlada-Government

Ministria e Shëndetësisë-Ministarstva Zdravstva-Ministry of Health

Bordi për licencim të profesionistëve shëndetësor, në bazë të nenit 15 të Udhëzimit Administrativ (QRK) Nr.10/2022 Për licencimin e profesionistëve shëndetësore të huaj, bazuar në Vendimin Nr.05 – 5248, datë 18.10.2022, Vendimin Nr.05- 5460, datë 27.10.2022 dhe Vendimin Nr. 05-6297, datë 02.12.2022, duke vendosur sipas kërkesës të Shërbimit Spitalor Klinik Universitar të Kosovës Nr.prot. 05 -6367, datë 11.10.2023, në takimin e mbajtur me datë, 16.10.2023, merr këtë:

V E N D I M

1. Shërbimit Spitalor Klinik Universitar të Kosovës për qëllime humanitare i lejohet angazhimi i profesionistëve shëndetësor të huaj Osteopatë - Pediatrik: z.Tommaso Ferroni, z.Federico Fiorita, znj.Romina Schievenin, znj.Allessia Boccaccino.

2. Profesionistëvë shëndetësor të huaj nga pika 1 e këtij vendimi i lejohet angazhimi nga data 09/11/2023 deri me datë 12.11.2023 në pajtim me Udhëzimin Administrativ (QRK) Nr.10/2022 Për licencimin e profesionistëve shëndetësor të huaj.

3. Shërbimi Klinik Universitar i Kosovë në pajtim me nenin 19 të Udhëzimit Administrativ (QRK) Nr.10/2022 Për licencimin e profesionistëve shëndetësor të huaj, është përgjegjës për dëmin eventual që i shkaktohet pacientit apo individit gjatë ofrimit të kujdesit shëndetësor.

A r s y e t i m

Shërbimi Spitalor Klinik Universitar i Kosovës ka parashtruar kërkesë me Nr.prot. 05 - 6367, datë 11.10.2023 në Bordin për licencim të profesionistëve shëndetësor për angazhim të profesionistëve shëndetësor të huaj - Osteopatë – Pediatrik: Dr.Tommaso Ferroni, Dr.Federico Fiorita, Dr.Romina Schievenin, Dr.Allessia Boccaccino për qëllime humanitare.

Bordi pas shqyrtimit të kërkesës së lartëshënuar dhe dispozitave ligjore në fuqi, konstatoj se janë plotësuar kushtet ligjore për angazhimin e përkohshëm të profesionistëvë shëndetësor për qëllime humanitare.

Kairospecial Pristina

The Kairospecial project of the Kairos association is based on the organization of a team of pediatric osteopaths trained at the Italian School of Pediatric Osteopathy – SIOP, who make themselves available every first Saturday of the month in 8 locations between Italy and Spain, to carry out osteopathic manipulative treatments to children with neuropsychiatric disorders completely free of charge. The project is expanding with more and more locations, all managed by a central secretariat for organizing the days.

The Pristina branch was also inaugurated in November, welcoming already discharged children returning for BMT or local children with trauma, pathologies or particular dysfunctions into the Pristina hospital. The Kairospecial Pristina days will be organized in conjunction with the Missions, on the same day and at the same times as the Kairospecial in any other national and international location.

kairospecial





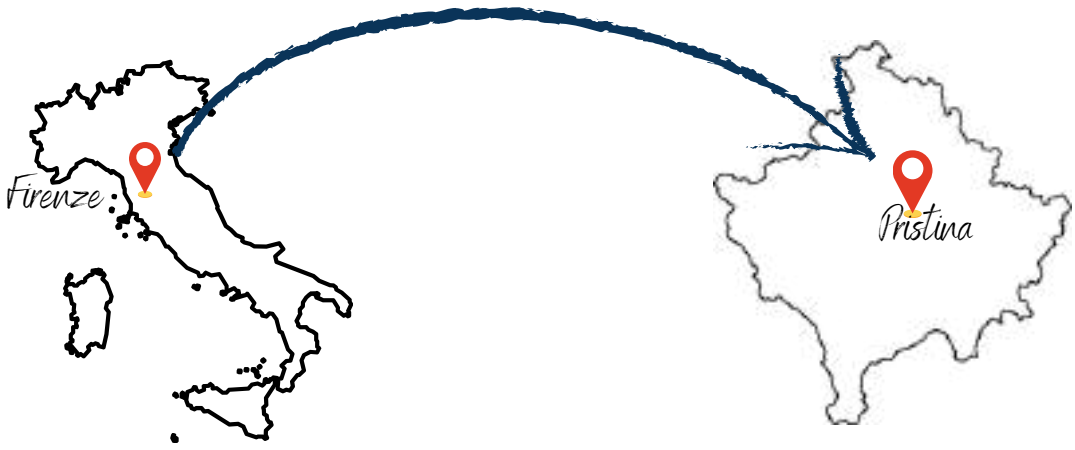

Future goals:

The dates of the 3 humanitarian missions which will take place in March, July and November have already been established in 2024, with the aim of further increasing them for the following year.

In the previous period, the objective will be to create a fixed agreement between the Kairos association, the Pristina Hospital and the Ministry of Health, in order to have an official national recognition for the work of pediatric osteopaths within all the departments as healthcare professionals authorized to carry out osteopathic treatments to young patients
.
Furthermore, communication will be established with the Head Doctors of each department, in order to treat hospitalized children and consult the Doctors with updated patient records and OMT each time.

This can also be carried out thanks to the Kairospecial day where children who have already been treated but have been discharged will be able to return any time. The data collected can be used as the basis for medical-scientific research.

The long-term objective will then be the training of the local team, with a preliminary study of the professionals involved and the type of possible learning dedicated to osteopathic techniques.



MISSIONS 2024 IN PRISTINA

Tuesday 27 February - Saturday 2 March

Wednesday 3 - Monday 8 July

Tuesday 29 October - Saturday 2 November

kairospecial

OSTEOPATHS SUPPORTING HEALTH OF CHILDREN WITH SPECIAL NEEDS

Kairospecial is a project created by the APS Kairos Osteopathy and Integrated Medicine Association (www.kairos-osteopatia.it), which provides teams of pediatric osteopaths trained at the Italian School of Pediatric Osteopathy SIOP (www.siop-fi.it).

Every first Saturday of the month, osteopaths carry out osteopathic manipulative treatments to patients 0-18 years old with neuropsychiatric disorders in various locations in Italy and abroad, providing 12 osteopathic treatments per year completely free of charge.

Started in 2018 in **Lido di Camaiore**, the association's headquarters, thanks to the Kairos Osteopathy President and SIOP Director Tommaso Ferroni, Kairospecial project has increasingly expanded with the opening of another 5 offices in Italy in 2022: in **Florence, Rome 1 and 2, Padua, Bologna and Como**.

At the end of 2022, the first foreign headquarter was inaugurated in **Tarifa, Spain**.

In October 2023 another headquarter was opened in Rome, and in November 2023 it was inagurated the **Kairospecial Pristina** in Kosovo, which will have 3 dates already agreed in 2024 to treat children discharged from hospital with various pathologies.

At the end of 2023, there are **7 headquarters in Italy and 2 abroad.**

The objective of the project is to treat at the osteopathic level many children with neuropsychiatric pathologies, such as autism, Down syndrome, ADHD, Pandas syndrome, and many others, through highly qualified and specialized professionals in the pediatric field and especially experienced in the above syndromes. Kairospecial Day takes place simultaneously in all locations, which gather online before starting treatments and continue to work in synergy with all teams.

Osteopathic manipulative treatments in children and guys with neuropsychiatric disorders can help to support the patient's health and stimulate the physiological mechanisms of self-regulation, aimed at mitigating discomfort, agitation, constipation, sleep disorders, or other difficult situations.

In addition, the Kairospecial project is open to participation and collaboration with other associations and organizations to support the health of children and people with disabilities at shared times.

KAIROSPECIAL DAY TAKES PLACE EVERY FIRST SATURDAY OF THE MONTH

TARIFA

PRISTINA

Ass. Culturale Kairos Osteopatia e Medicine Integrate
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Tel. 3894831701 info@kairos-osteopatia.it - www.kairos-osteopatia.com

THE MEDICAL-SCIENTIFIC RESEARCH CARRIED OUT AT THE MEYER HOSPITAL BY THE PEDIATRIC OSTEOPATHS DIRECTED BY DR FERRONI

Effectiveness of Manipulative Osteopathic Treatment in the pediatric neurosurgical population, through evaluation hospitalization times, load pharmacological, school resumption and of pain

Observational study of 276 children by Florinda Fracchiolla1, Tommaso Ferroni1, Barbara Vanoli1, Marco Gori1, Daniele Ciofi2,Mirko Scagnet3, Federico Mussa3, Lorenzo Parents3

1 Physiotherapist, Osteopath c/o Meyer Hospital, Florence; 2 SOs Nursing Coordinator Nursing Research, at Meyer Hospital,University of Florence; 3 Neurosurgeon, Neurosurgery Center of Excellence, Meyer Hospital, Florence

Background

The Pediatric Neurosurgery Unit of the Meyer Hospital in Florence represents the coordination center of the Tuscany Region for the diagnosis and treatment of all neurosurgical pathologies arising in the neonatal and pediatric age.

Neurosurgery provides every need connected to this specialty through specific skills and equipment and multidisciplinary collaborations aimed at taking charge of the small patient as a whole, for the consolidation of the results obtained.

The importance of offering the patient adequate pediatric care has prompted the various departments to open treatment paths with other specialist figures, including the osteopath. Osteopathy is a complementary medicine that is spreading strongly in Italy and in the world. Growing clinical trials are exploring the effects of osteopathic manipulative treatment (OMT) in different age groups, from prematurity to adulthood, highlighting an interesting impact on the reduction of perceived pain. Recent publications have demonstrated in premature benefits of osteopathic manipulative treatment: improvement of bowel function, breast attachment, reduction of hospital stay, placebo effects associated with osteopathic manipulation, etc. In the pediatric range, published studies demonstrate the possible benefits for postural asymmetries, asthma, relief of infantile colic, obstructive apnea, attention disorders, etc. In adults, several studies have been performed evaluating the effects of osteopathic manipulative treatment on pain; many publications concern chronic low back pain, possible benefits on pain intensity, functional disability, health-related quality of life, functional recovery and drug consumption, recovery of visceral motility post-abdominal surgery, etc.

In the last 50 years, we have witnessed a great change in the medical-scientific community in the evaluation and management of the pediatric field, following the numerous anatomo-physiological and behavioral studies on pain. These studies demonstrate that as early as the 23rd week of gestation, the central nervous system is anatomically and functionally competent for nociception. Furthermore, with the same painful stimulus, the newborn perceives more intense pain than the adult. The evidence also tells us that painful stimuli not treated adequately in childhood can have important effects on the current and future prognosis of the young patient; being able to interfere on the control mechanisms of neuronal survival, with phenomena of cytotoxicity and apoptosis. In the field of pain, great attention has also been paid to the onset and management of post-operative pain, defined as acute pain, of variable intensity, proportional to tissue damage, of limited duration, with an active stress reaction , which is often associated with neurovegetative responses, with consequent sensory and mental repercussions. The persistence of

post-operative pain could be the cause of wound healing delays, lengthening of healing times, in some cases even mortality. Inadequately treated acute pain can take on the characteristics of chronic pain after a surgical procedure, if

the painful symptoms persist for more than two months, excluding malignant factors, previous chronic infections, non-definitive resolution of the reason for surgical access. Chronic post-surgical pain is a difficult clinical phenomenon to establish. Cross-sectional studies affirm a 13% incidence of the onset of chronic pain, mainly following pediatric orthopedic surgery.

It is clear that the complexity of the pediatric patient requires adequate evaluation and treatment of these aspects, through a multidisciplinary management of post-operative pain, through both pharmacological and non-pharmacological tools. In non-pharmacological therapies, there are complementary therapies such as osteopathy, which through manual manipulation can favor adequate pain management support, with possible limitations of the physical, neurovegetative, mental, emotional consequences of the child, linked to an experience surgical. The field of study care, to date, still remains little investigated. The aim of the study is to measure the possible effects of osteopathic manipulative therapy in the Pediatric Neurosurgery department of the AOU Meyer in Florence, through hospitalization times, the pain reliever pharmacological load as needed, post-discharge school-sports recovery, and the pre/post-osteopathic treatment pain trend.

Materials and methods

The retrospective observational study carried out at the neurosensory department of the Meyer Pediatric Hospital in Florence lasted 4 years, from November 1, 2014 to December 31, 2018. The aim of the study was to observe the effects of OMT in pediatric patients, aged between 3 months and 18 years

Primary objective of the study

To measure the effect of osteopathic treatment carried out after admission within 24 hours, within 48 hours, within 72 hours after surgery of the group of patients who received OMT, compared to the general trend of the department (non OMT), comparing the following outcome measures:

• hospitalization times (from acceptance of hospitalization to discharge);

• load of pharmacological therapy as needed, counted by the number of administrations per kg/day of paracetamol, from the end of the analgesic protocol (expected for 48 hours after surgery) until discharge;

• return to school and sports, 30 days after resignation.

Inclusion criteria

• Pediatric patients undergoing a single neurosurgical procedure, with pathologies of exclusive neurosurgical relevance of low, medium, high complexity
• One osteopathy session from admission within 72 hours of surgery
• Signed informed consent

Exclusion criteria

• Patients in DH.
• Patients transferred from/to other departments.
• Patients with multi-specialty surgeries.
• Patients with two or more neurosurgery procedures during their stay in hospital. • Patients who received an osteopathy session more than 72 hours after surgery.
• Patients who have not given consent to osteopathic manipulative treatment

Secondary goal

Evaluate the effectiveness of osteopathic manipulative treatment in perceived pain, through a pre/post survey of all osteopathy sessions carried out in the population belonging to the neurosurgical hospitalization department. The study of this measure includes the administration of one or more osteopathic sessions, throughout the hospitalization period, with and without neurosurgical intervention. The pediatric measurement scales used are those validated by age. The pain scale was administered, before the OMT, and immediately after the conclusion of the osteopathic session.

For the extrapolation of the data, mathematical averages were carried out, pre/post-treatment. For the analysis of the outcomes, the whole neurosurgical population was grouped by type of main pathology, such as tumors, dysraphisms, hinge syndrome, hydrocephalus, epilepsy, craniostenosis, trauma, other. During the observation period, all hospitalized children received the gold standard care protocol and a group of these patients (276) received manipulative treatment (OMT). The randomization of the groups was carried out for the biweekly presence (Tuesday-Friday) of the osteopathic team. The osteopathic treatment, lasting 30 minutes, was carried out in the hospital room. The manipulative techniques used are administered through a light touch in respect of the post-surgical tissues and aimed at supporting micro-mobility, ligament balance, rebalancing of the autonomic nervous system. For data extrapolation, hospital software and validated pain tests were used. The post-discharge telephone survey was carried out by the neurosensory department secretariat.

The expected result, at the conclusion of the study, is to find a different trend of the observed outcomes in the groups of patients with OMT due to pathology.

Results

At the end of the observed period, in the four years, the pediatric patients enrolled in the study were a total of 1,573. The subjects who received osteopathic treatment, adhering to the inclusion criteria, were 230 in the first 24 hours, 251 in 48 hours, 276 in 72 hours after the neurosurgical intervention. The 1,297 patients who did not receive OMT were used as a control group. For the evaluation of the secondary objective, the total number of osteopathic manipulative treatments performed during the hospital stay was 1,057 osteopathic sessions.

Hospitalization trend results

Table I shows by pathology the number of patients in the OMT control and osteopathic treatment group, from hospitalization within 24 hours of surgery. For each group, the mean hospitalization, standard deviation and delta (difference between the observed groups) are reported.

The mean hospital stay of the control group (n = 1,297) averaged 5 days, SD ± 4.03, the group of the population that received osteopathic treatment (OMT within 24 hours = 230) shows an estimated mean daily hospital stay of 5, 1 days, SD ± 2.61. The craniostenosis population (n = 285; OMT within 24 hours = 80) shows a mean hospital stay of 4.63 days, SD ± 2.4, the OMT group has an estimated mean hospital stay of 4.2 days, SD ± 1, 3, mean difference of -0.43 days. In cancers, (n = 175), the estimated mean hospital

stay
is 7.18 days, SD ± 7.85, in the osteopathic treatment cohort (OMT within 24 hours = 67), the estimated mean daily hospital stay is 6.7 days, SD ± 3.4. Table II shows the mean hospital stays of the control

group
and of the OMT group, which received osteopathic treatment from admission within 48 hours of surgery. In the delta column, the difference between the two groups for each category. In the general ward cohort (n = 1,297), an average daily hospitalization of 5 days is estimated, SD ± 4.03, the population that received osteopathic treatment (OMT = 251) shows an average daily hospitalization of 5.27 days, SD ± 3.1

Patologie NCH	Coorte generale (gruppo controllo)			Gruppo TMO entro 24 ore			Delta
	Numero pazienti	Degenza media	Deviazione standard	Numero pazienti	Degenza media	Deviazione standard	
Craniostenosi	285	4,63	2,4	80	4,2	1,3	-0,43
Disrafismi	104	6,2	2,9	26	6,3	2,9	0,1
Epilessia	**43**	**6,65**	**2,8**	**2**	**4**	**1,4**	-2,65
Idrocefalo	**224**	**4,6**	**2,5**	**15**	**4**	**1,3**	-0,6
Sindromi corniera	**185**	**4**	**1,41**	**30**	**3,7**	**1,1**	-0,3
Trauma	**31**	**4,9**	**4,6**	**2**	**4,5**	**0,7**	-0,4
Tumori	**175**	**7,18**	**7,85**	**67**	**6,7**	**3,4**	-0,48
Altro	250	4,17	3,74	18	5,88	2,9	1,71
Totali	1.297	5	4,03	230	5,1	2,61	

Patologie NCH	Coorte generale (gruppo controllo)			Gruppo TMO entro 48 ore			Delta
	Numero pazienti	Degenza media	Deviazione standard	Numero pazienti	Degenza media	Deviazione standard	
Craniostenosi	285	4,63	2,4	89	4,64	3,5	0,01
Disrafismi	104	6,2	2,9	29	6,3	2,8	0,1
Epilessia	**43**	**6,65**	**2,8**	**2**	**4**	**1,4**	-2,65
Idrocefalo	**224**	**4,6**	**2,5**	**20**	**4,1**	**1,2**	-0,5
Sindromi corniera	**185**	**4**	**1,41**	**31**	**3,7**	**1**	-0,3
Trauma	**31**	**4,9**	**4,6**	**2**	**4,5**	**0,7**	-0,4
Tumori	**175**	**7,1**	**7,85**	**60**	**6,7**	**3,4**	-0,4
Altro	250	4,17	3,74	18	5,88	2,9	1,71
Totali	1.297	5	4,03	251	5,27	3,16	

Patologie NCH	Coorte generale (gruppo controllo)			Gruppo TMO entro 72 ore			Delta
	Numero pazienti	Degenza media	Deviazione standard	Numero pazienti	Degenza media	Deviazione standard	
Craniostenosi	281	4,43	2,4	80	4,26	3,3	-0,17
Disrafismi	184	6,2	2,9	31	6,2	2,7	0,0
Epilessia	43	6,65	2,8	3	6,6	4,7	-0,05
Idrocefalo	224	4,6	2,5	22	4,45	1,6	-0,15
Sindromi cerebrali	185	4	1,41	34	3,88	1,1	-0,12
Trauma	31	4,0	4,6	3	4,66	0,5	0,24
Tumori	175	7,18	7,85	65	6,98	3,6	-0,2
Altro	290	4,17	1,74	19	6,01	2,9	1,88
Totali	1.297	5	4,03	236	5,43	3,19	

Table III.

General hospitalization trend - OMT within 72 hours of neurosurgical intervention.

In epilepsy, the general population (n = 43) shows a mean daily hospital stay of 6.6 days, SD ± 2.8; patients who received OMT (OMT = 2) show a mean hospital stay of 4 days, SD ± 1.4. Table III shows the mean hospital stays of the control group and of the OMT group that received an osteopathic session after admission, within 72 hours of surgery. In the delta column, the difference between the two groups for each category. In the general ward cohort (n = 1,297) a mean hospital stay of 5 days was estimated, SD ± 4.03; for the osteopathic treatment group a mean of 5.43 days, SD ± 3.19. The statistical significance test performed on the observations at 24, 48, 72 hours showed a $p > 0.05$, highlighting that the clinical differences are not supported by statistical significance. Figure 1 and Table IV illustrate the trend of the average daily hospital stay (Tabb. I-III) among the disease populations most sensitive to OMT, between the control group and the group that benefited from osteopathic treatment, in the 24 hours, in the 48 hours, in the 72 hours post-surgery

Description pharmacological administration of paracetamol as needed

Table V shows the average administration units of paracetamol as needed, counted from the end of the post-operative analgesic protocol to discharge. Antalgic protocol in progress at the time of the osteopathic session. The Table shows for each category the number of patients in the control and osteopathic treatment groups, from hospitalization within 24 hours of surgery. For each group, the mean hospitalization, standard deviation and the delta (difference between the observed groups) are reported. The control group (n = 1,291) required an average of 1.01 units of as-needed paracetamol, SD ± 1.2. The cohort of OMT patients (OMT within 24 hours = 226) presented on average an administration of 0.9 units of administrations, SD ± 1.8. In craniostenosis (n = 285; OMT = 79), mean course of drug administration for the group = 0.6, with SD ± 1.2; for the OMT group = 0.4, with SD ± 1, mean -0.2 difference. In hydrocephalus (n = 221; OMT = 15), the mean dose units for the group = 0.79, SD ± 1.64; for the OMT group mean administration, with SD ± 0 and p-value = 0.06. For trauma (n = 31; OMT = 2), mean drug administration units = 0.8, SD ± 2.27; OMT cohort does not receive as-needed drug administration. Table VI shows the average administration units of paracetamol, as needed, counted from the end of the post-operative analgesic protocol to discharge. Antalgic protocol in progress at the time of the osteopathic session.

The Table shows for each category the number of patients in the control and osteopathic treatment groups, from hospitalization within 48 hours of surgery. For each group, the mean hospitalization, standard

deviation and the delta (difference between the observed groups) are reported. The control group (n = 1,291) required an average of 1.01 units of as-needed paracetamol, SD ± 1.2. The cohort of OMT patients (OMT within 48 hours = 271) presented on average an administration of 1.03 units of administrations, SD ± 1.8.

In hydrocephalus (n = 221; OMT = 20), the mean dose units for the group = 0.79, SD ± 1.64; for the OMT group mean administration = 0.35, with SD ± 0.74. Table VII shows the average administration units of paracetamol, as needed, counted from the end of the post-operative analgesic protocol to discharge. Analgesic protocol concluded at the time of the osteopathic session. The Table shows for each category the number of patients in the control and osteopathic treatment groups, from hospitalization within 72 hours of surgery. For each group, the mean hospitalization, standard deviation and the delta (difference between the observed groups) are reported. The control group (n = 1,291) required an average of 1.01 units of as-needed paracetamol, SD ± 1.2. The OMT cohort (OMT within 72 hours = 271) had an average dose of 1.1 units of doses, SD ± 2. In hydrocephalus (n = 221; OMT = 22), the mean dose units for the = 0.79, SD ± 1.64; for the OMT group mean administration = 0.31, with SD ± 0.71, with a mean difference of -0.48. The statistical significance test performed on the observations at 24, 48, 72 hours showed a $p > 0.05$, highlighting that the clinical differences are not supported by statistical significance. Figure 2 and Table VIII illustrate the trend in the administration units of the pharmacological load as needed (Tabb. V-VII) among the disease populations most sensitive to OMT, between the control group and the group that benefited from the treatment osteopathic, in the 24 hours, in the 48 hours, in the 72 hours post-surgery.

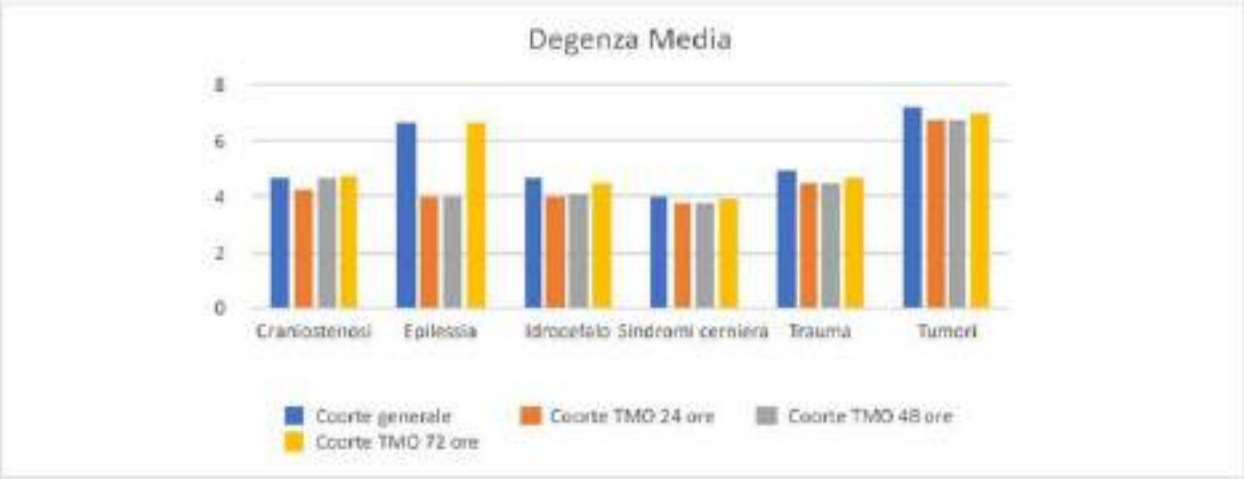


Figura 1.
Andamento degenza media nelle patologie maggiormente sensibili al TMO.

	Craniostenosi	Epilessia	Idrocefalo	Sindromi cerniera	Trauma	Tumori
Coorte generale	4,63	6,65	4,6	4	4,9	7,18
Gruppo TMO entro 24 ore	4,2	4	4	3,7	4,5	6,7
Gruppo TMO entro 48 ore	4,64	4	4,1	3,7	4,5	6,7
Gruppo TMO entro 72 ore	4,76	6,6	4,45	3,88	4,66	6,98

Tabella IV.
Andamento degenza media per patologie principali e tempo di somministrazione TMO post-neurochirurgia.

Patologie NCH	Coorte generale (gruppo controllo)			Gruppo TMO entro 24 ore			Delta
	Numero pazienti	Unità somministrazione media paracetamolo	DS	Numero pazienti	Unità somministrazione media paracetamolo	DS	
Craniostenosi	285	0,6	1,2	79	0,4	1	-0,2
Disrafismi	104	1,75	2,27	26	1,9	2,4	0,15
Epilessia	43	2,83	3,74	2	0	0	-2,83
Idrocefalo	221	0,79	1,64	15	0	0	-0,79
Sindromi cerniera	185	0,69	1,49	30	0,60	1,5	0,09
Trauma	31	0,8	2,27	2	0	0	-0,8
Tumori	173	1,72	2,94	54	1,8	2,3	0,08
Altro	249	0,8	1,7	18	1,6	2,1	0,8
Totali	1.291	1,01	2,03	226	0,9	1,8	0,1

Tabella V.

Patologie NCH	Coorte generale (gruppo controllo)			Gruppo TMO entro 48 ore			Delta
	Numero pazienti	Unità somministrazione media paracetamolo	DS	Numero pazienti	Unità somministrazione media paracetamolo	DS	
Craniostenosi	285	0,6	1,2	88	0,5	1,2	**-0,1**
Disrafismi	104	1,75	2,27	29	1,9	2,39	0,15
Epilessia	**43**	**2,83**	**3,74**	**2**	**0**	**0**	**-2,83**
Idrocefalo	**221**	**0,79**	**1,64**	**20**	**0,35**	**0,74**	**-0,44**
Sindromi cerebrali	**185**	**0,69**	**1,49**	**30**	**0,60**	**1,54**	**-0,09**
Trauma	**31**	**0,8**	**2,27**	**2**	**0**	**0**	**-0,8**
Tumori	**171**	**1,72**	**2,94**	**57**	**1,7**	**2,3**	**-0,02**
Altro	249	0,8	1,7	21	1,6	2,14	0,8
Totali	1.291	1,01	2	271	1,85	1,8	0,02

Tabella VI.
Andamento paracetamolo al bisogno generale - TMO entro 48 ore dall'intervento neurochirurgico

Patologie NCH	Coorte generale (gruppo controllo)			Gruppo TMO entro 72 ore			Delta
	Numero pazienti	Unità somministrazione media paracetamolo	DS	Numero pazienti	Unità somministrazione media paracetamolo	DS	
Craniostenosi	285	0,6	1,2	98	0,7	1,8	0,1
Disrafismi	104	1,75	2,27	31	1,9	2,22	0,15
Epilessia	**43**	**2,83**	**3,74**	**3**	**2**	**3,46**	**-0,83**
Idrocefalo	**221**	**0,79**	**1,64**	**22**	**0,31**	**0,71**	**-0,48**
Sindromi cerebrali	**185**	**0,69**	**1,49**	**33**	**0,57**	**1,47**	**-0,12**
Trauma	**31**	**0,8**	**2,27**	**5**	**0**	**0**	**-0,8**
Tumori	171	1,78	2,94	62	1,8	2,3	0,02
Altro	249	0,8	1,7	19	1,6	2,9	0,8
Totali	1.291	1,01	2	271	1,1	2	0,1

Tabella VII.
Andamento farmaci al bisogno generale - TMO entro 72 ore dall'intervento neurochirurgico

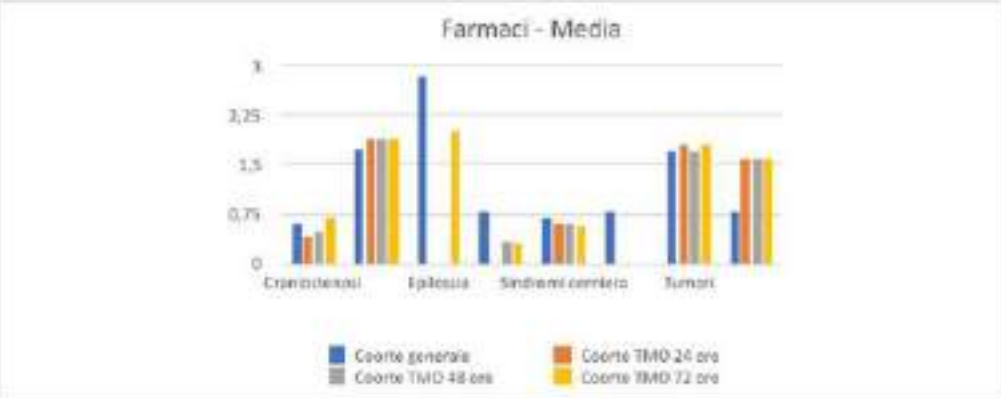


Figura 2.
Andamento del carico farmacologico nelle patologie maggiormente sensibili al TMO.

	Craniostenosi	Disrafismi	Epilessia	Idrocefalo	Sindromi cerebrali	Trauma	Tumori	Altro
Coorte generale	0,6	1,75	**2,83**	**0,79**	**0,69**	**0,8**	1,72	0,8
Coorte TMO 24 ore	**0,4**	1,9	**0**	**0**	**0,6**	**0**	1,8	1,6
Coorte TMO 48 ore	**0,5**	1,9	**0**	**0,35**	**0,6**	**0**	**1,7**	1,6
Coorte TMO 72 ore	**0,7**	1,9	**2**	**0,31**	**0,57**	**0**	**1,8**	1,6

Tabella VIII.
Media somministrazione Paracetamolo al bisogno per patologie principali e somministrazione TMO post-neurochirurgia.

Telephone survey

30 days after discharge, the entire population (n = 1,291, TMO = 276) adhered to the telephone interview. The data on school/sports recovery was acquired through a verbal question, with an affirmative/no result. For a more detailed analysis, the study population was grouped by age group, preschool (0-5 years), school (6-11 years and 12-14), adolescent (≥ 15 years).

The number of patients (n) and OMT by age group, the number of patients (n) and OMT returned to school, and the relative percentage were calculated (Table IX). The 0-5 age range includes attendance at nursery
schools and nursery schools, 11 patients belonging to the general group (n = 732) returned to school, incidence 1.50%. In the OMT group (n = 121), 9 patients returned to school within 30 days of discharge, incidence 7.44%. The 6-11 age range includes school attendance at primary schools, patients (n = 235)
returned to school were 19, incidence 8.08%; of the OMT group (n = 66) 13 patients returned, incidence 19.70%. The 12-14 age range includes school attendance at compulsory schools, 7 patients (n= 134) returned to school, incidence 5.22%. In the OMT group (n = 43) 8 patients returned, incidence 18.60%

Fascia età popolazione neurochirurgica	Gruppo generale controllo (n)	Numero pazienti rientrati	%	Gruppo TMO	Numero pazienti rientrati	%	P-value
0-5 anni	732	11	1,50	121	9	7,44	0,013
6-11 anni	235	19	8,08	66	13	19,70	0,006
12-14 anni	134	7	5,22	43	8	18,60	0,0002
≥ 15 anni	190	15	7,89	46	11	23,91	0,003
Totale	1.291	52	4,03	276	41	14,85	

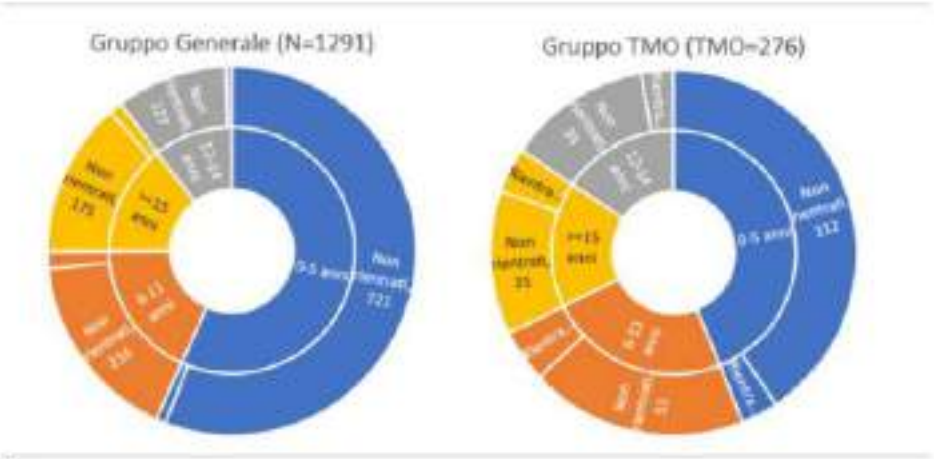
Table IX.

Resumption of school attendance 30 days after post-neurosurgery discharge.

The age group ≥ 015 years, includes attendance at secondary schools, patients (n = 190) returned to school were 15, incidence 7.89%. OMT patients (n = 46) returned to school were 11, incidence 23.91. Overall, the ward's recovery percentage is 4.02% on the 30th day after discharge. In the OMT group, osteopathic treatment seems to favor school resumption by 14.85%. The significance test for each school age group shows a $p < 0.001$, highlighting statistical significance. The resumption of sports attendance at 30 days did not reveal any noticeable signs (Fig. 3).

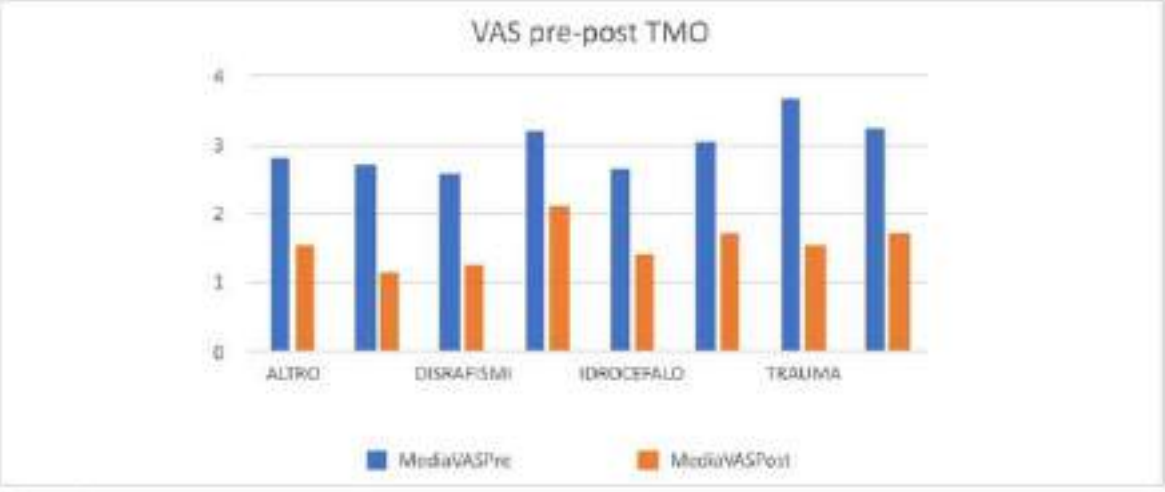
Overall study of the mean change in perceived pain pre/post-OMT

Table X includes all the neurosurgical population that received OMT in the 4-year study. For each category, the number of osteopathic treatments performed, the mean value of the pre/post-OMT pain scale, and the relative difference are reported. Osteopathic treatments carried out in hospitalized neurosurgical patients totaled 1,057. The general trend shows a reduction in the mean pre/post pain score on the administered scales of -1.49.



Patologie NCH	Coorte TMO			Delta
	TMO effettuati in degenza	VAS media pre-TMO	VAS media post-TMO	
Craniostenosi	105	2,7	1,16	-1,49
Disrafismi	96	2,57	1,26	-1,22
Epilessia	11	3,3	2,11	-1,44
Idrocefalo	94	2,62	1,42	-1,2
Sindromi cerebriera	54	3,02	1,72	-1,32
Trauma	24	3,65	1,55	-2,1
Tumori	155	3,65	1,55	-2,1
Altro	518	2,8	1,55	-1,2
Totali	1.057	3,03	1,54	-1,49

Tabella X.
Andamento medio VAS pre/post-TMO.



Qualitative collection of pre/post-OMT experience

In the 4 years a first qualitative descriptive collection was carried out, collecting the observations reported or observed, during or after OMT by the child and/or by the parent or guardian, when spontaneously expressed. In children aged 0-5 years, the frequently reported sensations are those of facilitation towards a state of relaxation, calm and reduction of post-surgery irritative states. Patient relaxation was frequently observed during OMT, in stressful situations, in the two hours before surgery or upon return to the hospital room, after post-surgical anesthetic awakening. Quite frequently, a facilitation in the channeling of gases and in the emptying of the hive is reported. Two cases were observed, 3-year-old and 4-year-old females with spina bifida, who during osteopathic treatment expressed a desire to empty the bladder without the need for intermittent catheterizations. In the 6-12 year age group, the sensations reported or observed are facilitation of relaxation, night rest, increased vitality and resumption of spontaneous play, reduction of pain. Over the age of 12, children frequently report a feeling of well-being and relaxation.

Discussion

The study conducted allowed us to observe variations in all the observed outcomes. The subdivision by main pathology groups, such as craniostenosis, epilepsy, hydrocephalus, hinge syndrome, trauma, tumors, highlighted which categories and age groups show greater sensitivity to OMT. The administration of osteopathic treatment within 24, 48, 72 hours after neurosurgical intervention, on the other hand, demonstrates how OMT could modify the outcomes. In particular, the average hospitalization trend, clinically influenced by OMT, can be further reduced if the manipulative treatment is administered within 24 hours, as observed in craniostenosis (average ward hospitalization 4.63 days, average OMT hospitalization within 24 hours , 4.2 days), in epilepsies (average ward stay 6.65 days, average OMT stay within 24 hours, 4 days). The outcome measures remain encouraging, in the administration of OMT within 48 hours of surgery, such as for epilepsy (average ward stay 6.65 days, average OMT stay within 24 hours, 4 days), for hydrocephalus (average ward stay 4, 6 days, mean OMT stay within 48 hours, 4.1 days) etc. In 72 hours the effects of OMT seem less strong, perhaps because they are close to discharge, except for trauma, tumors and hinge syndromes. Even the average trend of the analgesic administration units (paracetamol as needed) can be clinically influenced by the time point in which the OMT is administered; Figure 2 shows the most sensitive categories. Epilepsies, for example, show greater benefit if OMT is administered within 24 hours [average pharmacological as needed general (pts = 43), 2.83 administrations, average OMT pharmacological within 24-48 hours (pts = 3), none administration request], as the benefits become less evident if OMT is administered within 72 hours. Hydrocephalus (pts = 221) seems to benefit from drug reduction if OMT is performed within 24-48 hours (pts = 20), with a p-value close to statistical significance. The telephone survey, after 30 days, made it possible to investigate the possible effects of OMT on school and/or sports recovery. From the results that emerged, the ward recovery percentage on average is 4.02%
on the 30th day after discharge for the OMT group, the recovery percentage is 14.85%, also confirmed by statistical significance. The data is confirmed for each age group, from pre-school to all levels of schooling. In the age group ≥ 15 years, patients who received OMT show a 23.91% return-to-school incidence, compared to the control group (n = 7.89%). From the same survey method it was not possible to evaluate sports recovery, probably due to the short observation time, even if it was recommended upon resignation. The analysis of the average perceived pain, pre/post-OMT, carried out for all the osteopathic treatments administered during the stay in the ward (for diagnostic purposes, with/without surgery), showed an average pre/post reduction in pain perceived across the neurosurgical population of -1.49 on the pain scale. Tumors (OMT performed = 155) and trauma (OMT = 25) show an average reduction in perceived pain

of 2.1 in the score of the rating scales. In this study, a preliminary and simple qualitative collection of the effects observed or spontaneously reported by patients or parents was carried out, during or at the end of osteopathic treatment. In children aged 0-5 years, the frequently reported sensations are those of facilitating a state of relaxation, calm and reduction of post-surgery irritative states. Patient relaxation during OMT was also frequently observed in pre/post-surgery stressful situations. In the 6-12 year age group, the reported sensations are of relaxation, increased vitality and return to spontaneous play. Over the age of 12, the child reported feeling well and relaxed. Qualitative collection could be implemented by validated tools for measurement.

Conclusions

The study conducted allowed, first of all, to determine the variations in the measured indicators and to evaluate Osteopathic Manipulative Therapy, clinically useful in improving hospitalization times and pharmacological load when needed; statistically significant in favoring the return to school of the pediatric population. Secondly, the reduction of pain and the qualitative collection of the perceived experience in patients treated with OMT support the hypothesis that osteopathy can be useful in supporting post-surgical pediatric care.

Limits

• Limitations of the study are represented by the inhomogeneity of the population observed by age and degree of complexity of the pathology
• The non-daily presence of the osteopath did not allow a standardization of the number of sessions for each patient
• Difficulty in comparing the pre/post-OMT pain averages with the general ward pain averages, in order to be able to build a rationale and better observe the trends.

The future prospects could be to expand the sample or to plan a more appropriate osteopathic treatment plan for the post-surgical days. And use validated tools for the qualitative collection of the perception of osteopathic treatment and quality of life, in order to offer greater strength to the results obtained.

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HSOA Journal of Community Medicine and Public Health Care

Research Article

Osteopathic Treatment in Adult Patients Whit Hemoglobinopathies: A Coort of Study for Pain Evaluation and Quality of Life

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Abstract

Background: WHO estimates 180 million Hemoglobinopathies individuals worldwide, 7244 in Italy. Iron overload from transfusion ther- apy causes severe organic complications.

Objective: To evaluate the use of OMT, on the cohort of adult patients to assess pain and QoL.

Methods: Patients enrolled received a 30' OMT, once a week for 2 weeks, every 15 days for three weeks. VAS administered for pain measurement and SF36 for QoL, Before-After OMT. The convenience sampling with 10 enrolled subjects. The Pediatric Ethics Committee approved.

Results: Eight subjects enrolled. At the first detection, the mean pain reported 7 SD+-2.39, at the last detection of the after-OMT, it was 0.38 SD+-0.52.

The VAS difference between the first treatment and the second was 4.75 (P<0.0002), and 6.63 after the 5th (P<0.0001). For the QoL, we highlight average 88.6 SD+-14.26; 97.6 SD+-15.16, at the end of the treatment, P=0.43.

Conclusion: The study highlights the usefulness of OMT in the treatment of osteoarticular pain. For QoL, the improvement is not statistically significant.

The results we obtained highlight the efficacy of OMT in adults with BTM, especially in pain reduction, positively influencing QoL. An increase in the sample and an RCT study would be useful.

Keywords: Hemoglobinopathies; Osteopathic manipulative treatment; Pain; Thalassemia; Quality of life

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Introduction

Thalassemic syndromes are a heterogeneous group of anemias of an autosomal recessive hereditary nature, caused by mutations affecting the genes of the protein chains of hemoglobin.

Beta Thalassemia (BT) is characterized by the deficit or total absence of the synthesis of beta-globin chains, which encodes the Hemoglobin Protein (Hb). Beta Thalassemia Mayor (BTM) or Cooley disease, is the homozygous form of BT and is associated with microlitic, hypochromic anemia and splenomegaly, due to dyseritropoiesis and hemolysis [1].

The World Health Organization (WHO) has estimated the presence in Europe, Africa and Asia of about 180 million microcitemic individuals, of whom 40% are healthy carriers of BT [2]. In Italy it is estimated that there are almost 2.5 million healthy carriers, that is, people who carry the genetic defect, who do not exhibit symptoms [3]; in particular, 7000 cases have been recorded [4] with a prevalence that reaches 15-20% in some Regions (Sicily, Sardinia) and in specific territories (for example Po Delta) [5].

As reported by the Rare Diseases Observatory, there are different types of thalassemia: in Africa, alpha thalassemia is more widespread (reduced synthesis of alpha chains), while in the Mediterranean basin beta (more reduced synthesis of beta chains) is more widespread, called also Mediterranean Anemia [6].

In the VI Congress of the Italian Thalassemia and Hemoglobinopathies Society (SITE), specialists defined thalassemia as an "emerging disease". From the census conducted between 2008 and 2010 in the 134 Italian centers, which deal with thalassemia, 7244 sufferers, with an increasing trend due to the presence of immigrants from areas of the globe where the pathology is endemic [7].

The onset of the disease occurs between 6 and 24 months of life and presents with severe anemia, which requires systemic transfusions to keep the Hb at the level of 90-100 g / l, so as to allow carrying out the normal physiology of the organism [8]. However, the transfusion of concentrated Red Blood Cells (RBC) is the cause of a progressive iron overload which, if not removed, leads to serious complications of various organs (mainly the heart, liver and endocrine glands) [9]. The treatment of BTM involves periodic transfusion RBC, generally every two to three weeks, and treatment with ferro-chelating drugs, such as: Deferoxamine, Deferiprone, and finally Deferasirox, available in Italy since 2007, which provides for a single daily administration with demonstrated ferrochelation in all the organs involved.

In thalassemia patients there are numerous musculoskeletal and osteoarticular problems: splanchnocranium enlargement, spinal de- formity, scoliosis, compression of peripheral nerves, spontaneous fractures, loss of bone mass, analgesic contractures, myalgias, etc.

While the side of the disease, that is the etiopathogenetic component of the disease with its possible complex therapies, is extremely studied, the person's experience and Quality of Life (QoL) is less investigated. The most popular sources of information and dedicated websites deal precisely and precisely with the mechanics of the disease and its therapy, but do not take into consideration the psychological, emotional, social, relational, affective, working and economic aspects of the thalassemic patient. The side of illness - that is, living with disease - can only be investigated by listening to the voices of those who experience the disease and treatments firsthand, to understand what their true basic needs are, beyond the limits intrinsic data from the disease, and how partially they can be satisfied [10]. In southern Iran, a cross-sectional study on the usefulness of complementary medicines in thalassemia patients in Shiraz has recently been published, through the use of natural herbal products to help patients reduce serum ferritin and iron load in patients [11].

In December 2015, a report entitled 'The Value for the person with BTM was released by the SITE; a project to analyze the social cost and the tools to live with the disease, which analyzes emotional, emotional and lived aspects, both from the patient and the caregivers' point of view, highlighting the complexity of the disease and the goals achieved [12].

Currently in high development countries people with thalassemia have a life expectancy and quality standards of the same similar to the healthy population, provided that they can access an adequate treatment regime. It is important to underline that integration with other professional figures has also led to significant progress in understanding pathology and treatment.

From the analysis of the literature, Thalassemia is a disease that is not very well studied and discussed, especially in some areas, such as nursing and even less, from an osteopathic point of view [13-14]. At the moment our territory does not yet have numerous specialist centers for the diagnosis and treatment of these patients, as the pathology itself is not very widespread and, precisely for this reason, it has proved difficult to face a study that reaches conclusions today clinical and therapeutic aspects of maximum certainty [15].

The birth of scientific societies such as SITE, have the aim of being able to fill these shortcomings present in the scientific world, through the publication of evidence of efficacy in support of assistance to patients suffering from a pathology with such high dependence. At the pharmacological level, many progresses have been made, but the priorities linked to the general state of health of the thalassemic patient, due both to its clinical situation and to the complications related to the type of treatment, still remain very high; among which osteo-articular pain caused by ectopic extra-medullary localization factors, arthrosis, arthritis from iron accumulation and osteoporosis-osteopenia from endocrinopathies [16].

The Meyer pediatric hospital in Florence, within the Pediatric Cancer and Stem Cell Transplant department, offers a clinical care pathway for patients suffering from thalassemia and Hemoglobinopathies. To date, there is a cohort of adult patients who report functional musculoskeletal limitations, with a consequent reduction in daily life activities and an increase in painful perception.

In order to address these aspects within the treatment path, the Osteopathic Manipulative Treatment (OMT) was recently introduced, enriching the multi-professional team of the osteopath. Osteopathy is based on the consideration of the person as a unit, or the whole of the body, mind and spirit; and on the ability of the 'body' system to make corrections, restoring balances, through the mechanisms of self-regu- lation, physiologically already present within it. Great importance is attached to the relationship between structure and function, two in- terdependent aspects [17]. Osteopathy uses the 'manipulative touch' to support the patient's health [17]. Touch plays a crucial role in rela- tionship in both children and adults [18]. The empathic relationship with the patient is an essential condition for the success of osteopathic treatments [19]. Also Touch has an affective and symbolic function [20]. It is a highly complex sensory modality. Perception of stimuli varies from person to person based on life experiences and genet- ic and epigenetic factors [21]. Human touch seems to attenuate the physiological response to stress in children and decreases the expres- sion of cortisol [22], regulating oxytocin, vasopressin [23], and vagal tone [24]. Studies show that touch, used in osteopathic techniques, is an expression of compassion, skill and competence [25]; probably encourages the DNA to behave differently, promoting mitochondrial biogenesis, with possible effects on the reduction of the inflammatory state [26], on the attenuation of the sensation of stress and perceived pain, on the improvement of mood and increase in self-confidence and towards others, with cascading effects on pro-social behaviors [27].

Osteopathic manipulative touch is targeted and reflexive, palpation has an impact on the musculoskeletal, immune, endocrine, neuropsychic systems [28,29]. Through the touch, stimulation is produced on the skin, which represents the first delimiting structure of the body, the interface between inside and outside. It is the first physical barrier to potentially negative stimuli (antigens), with an efficient immune system capable of organizing a specific immune response by dendritic cells [30]. The immune response is a normally systemic response that involves system sectors located in areas of the body. It is not possible to separate the immune cell from its context and from the influences exerted by the environment in which it operates, consisting of vessels, nerves, cells, substances and tissue structures, whose messages are represented by hormones, neurotransmitters, cytokines and other substances biologically active, being a system in constant motion [30]. Recent studies show how osteopathic manipulation can act on the connective fascia, which, having its own contractility potential [31], can produce effects in musculoskeletal dynamics [32].

Inflammation also represents a complex phenomenon, which starting from stimuli of an infectious, chemical, physical, immune, psychic nature involves vessels, tissues, organs and systems, and is regulated by intrinsic mechanisms, by cytokines, chemokines and immune cells, nervous and endocrine circuits [29]. The noxious, irritating, thermal stimulus reaches the underlying nerve endings (the C fibers) which release chemicals, substance P, a neuropeptide that transmits the pain signal in the brain, but is not only a pain messenger, as it has a role of activator of the inflammatory response by immune cells present in the dermis [31,33].

For some years, in chronic, post-traumatic stress-induced, affective diseases, the phenomenon of interception has been observed, as a multidimensional construct, together with the phenomenon of sensitization, defined as an amplification response, having a neurological basis following of repeated stimuli, and the possible applications of manual therapies [34].

Touch-based manual practices, especially osteopathy, seem to produce anti-inflammatory and hyper-parasympathetic effects, offering an alternative method [...] to modify temporary or permanent sensitization states for the entire duration of the interaction with the treatment of peripheral tissues.

This is supposed to produce a biological and neurological cascade of events that modify the interoceptive processes, interrupting the vicious circle of a low-threshold and persistent inflammatory condition [34,35].

The study of this approach, applied in these pathologies, however, represents a gray area, worthy of investigation.

The goal of our research was to measure, through an observational survey, the possible effects of osteopathic manipulative therapy on the pre-post treatment pain trend, and the QoL of patients suffering from anemia, treated at the center Florentine, especially on those affected by BTM.

Materials and Methods

The study was based on measuring the possible effects of OMT, administered once a week for the first two weeks, every 15 days for the three consecutive weeks, with duration of 30 minutes. The detec- tion was carried out through the use of validated evaluation scales, such as: Visual Analogic Scale (VAS) for Before-After treatment pain and the 36-item short-form SF-as a questionnaire to measure the qual- ity of patient's life [11], Before-After osteopathic treatment cycle.

For convenience, given the rarity of the pathology and the small size of the sample, the entire population affected by Thalassemia Mayor and Intermedia has been included, being treated at the DH Oncohaematological service of the Meyer Pediatric Hospital in Florence. Twenty-five of the thirty-five subjects in charge of the aforementioned department were enrolled on the basis of the following inclusion criteria: Presence of osteo-articular pain, osteoporosis, functional limitation, declared unsatisfactory QoL; and exclusion: tumor pathologies, suspected bleeding condition, damage to the integrity of a bone, and / or tendon, and / or ligament, and / or joint, suspected malformation or cerebral hemorrhage, psychiatric diseases or mental limitations, the lack of knowledge of Italian language, minors and teenagers aged 25 or under. A sample size of ten enrolled units had been established, based on the prevalence of beta thalassemia in the Tuscany region. However, our evaluation was performed on a sample of only eight units, due to the logistical difficulties that occurred during the study period (Figure 1).

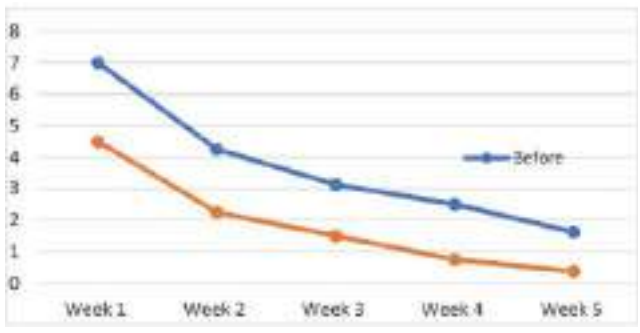

Figure 1: Before-After OMT Pain Trend.

The sampling was of convenience structured on voluntary participation upon receipt of written informed consent. The study took place in the period from 13 November 2015 to 1st October 2017.

The research was in accordance of Helsinky Declaration. The protocol was approved by the pediatric ethics committee of the Tuscan region on 12 November 2015.

At the time of enrollment, the patient was included in the study: pain was detected by VAS scale and QoL was measured through the FS36 questionnaire at zero time.

Subsequently, the patient underwent a 30-minute OMT session, weekly for the first two weeks, every 15 days for the following 3 weeks, and a total of 5 osteopathic manipulation sessions. The pain symptom was measured before and after each session and the QoL was measured again at the end of the session.

The data were collected anonymously using special forms, assigning a numerical code to each patient (for example 001) and entered in an anonymized database, suitably pre-established through the EXCEL calculation program and processed in an aggregate manner with the EPINFO statistical program. The confidence interval (I.C.) used was 95%, the P value less than 0.05. The variables were assessed on the basis of their frequency and their means, the qualitative ordinal and nominal ones subjected to the Chi2 test, the quantitative ones assessed with Student's T test for parametric data and ANOVA for the analysis of variance; if the test is not parametric, the variance with the Kruskal-Wallis test will be evaluated. The data will be crossed to establish the relationship between the score of the answers and the demographic and anamnestic characteristics.

The study does not aim to generalize the data to the whole thalassemia population, but to evaluate the effectiveness of a treatment still with scarce evidence. However, it may be useful for promoting future studies.

Results

There were 8 subjects enrolled. The analysis of the data showed that the sample consisted of 1 male and 7 female patient, one of whom was pregnant at 22+5 weeks of gestation. The average age is 41.8 years DS+- 6.8. Out of 8 enlisted subjects, two are unemployed while one is not responding; in most cases (five) it is paperwork, one of which is a freelancer, currently unemployed. The survey participants almost all present one or more hobbies, only two do not respond, most of them have a hobby that physically engages them in activities, such as walking. Most of the respondents are affected by Thalassemia Mayor, only one person has Blackfan-Diamond syndrome. Seven out of eight subjects have active or past co-morbidities of some impor- tance including: HCV infection, stroke, diabetes, cirrhosis, osteopo- rosis and dysmenorrhea.

Six out of eight patients have joint pain, seven out of eight have previous trauma, iron chelation therapy is present in most of the participants, and one person uses antidepressants.

Results of pain perception data: Pain was measured with the VAS scale before and after each osteopathic treatment, for all 5 sessions weekly.

At zero time (first detection performed before the first treatment) has an average pain of 7 DS+-2.39, ranged between 4 and 10, median 7 modes 4 emerged. The last post-treatment detection indicates an

average perceived pain value of 0.37 DS +- 0.52, range between 0 and 1, median0 mode 0. (Table 1) Shows the average values on the perception of pain before and after osteopathic treatment, for each session of the treatment cycle.

Before-After OMT - VAS detection per cycle of five sessions					
	Be-fore	After 5 Day	Differ-ence	DS	P Value
Before OMT average time 0 and after 1 treatment	7	4,5	2,5	+- 2,39	0,068
2 before OMT average and after 2 treatment	4,25	2,25	2	+- 1,91	0,02
3 before OMT average and after 3 treatment	3,125	1,5	1,63	+- 1,45	0,01
4 before OMT average and after 4 treatment 0,001	2,5	0,75	1,75	+-1,07	0,001
5 before OMT average and after 5 treatment	1,625	0,375	1,25	+- 0,52	0,02

Table 1: Osteopathic Manipulative Treatment (OMT) and Visual Analogic Scale (VAS).

In the table two shows the numerical values of the average of the VAS scale relating to the perception of pain deriving from the comparison of the Before-After single osteopathic treatment value, for the entire cycle of treatments, five sessions of manipulative therapy, the first two weekly, the following three, every fifteen days. (Table 2)

Mean Difference of Pain Perception before treatment 1 and after subsequent treate-ments OMT			
	average difference best perception pain	DS	P Value
Mean difference before 1 after 2	4,75	+- 1,39	0,00025
Mean difference before 1 after 3	5,5	+- 1,19	0,0000
Mean difference before 1 after 4	6,25	+- 0,71	4
Mean difference before 1 after 5	6,63	+- 0,52	0,0000
			1
			0,0000
			1

Table 2: Above graph one, shows the trend of the values mentioned in table two.

Results of perception of QoL data: The 36-item short-form scale (SF-36) was used, administered before starting the cycle of 5 treatments (T0) and at the end of the cycle itself. Out of 8 observed param- eters, the following was highlighted:

• At zero time an average 88.6 SD + - 14,3, range 74.1 - 119.3, median 86.3 and mode of 74.1.

• At the end of the treatment cycle an average of 97.6 SD + - 15.2, range between 76.2 and 123.8, median of 98.9, mode of 76.2.

Table number three shows the detailed values concerning each item making up the FS36 scale and the total of the values. At Student's T test, a value of P = 0.42 is highlighted.

Table number four shows the average values for each item and the total of the averages. At the student's T test, a value of 0.43 is highlighted (Tables 3 & 4).

QoL score comparison before OMT and post OMT cycle (five sessions)		
	total PRE	total POST
Physical activity value	88,1	107,8
Role value and physical health	74,1	85,2
Physical pain value	95,5	85,6
Health value in general	77	104,5
Vitality value	80,3	96,5
Value Social activities	119,3	123,8
Role and emotional state	90,1	101,2

Table 3: The detailed values concerning each item making up the FS36 scale.

Average QoL score comparison Before OMT and After OMT cycle (five sessions)		
	Averages Before	Averages After
Average physical activity BEFORE	65,6	70
Average role value and physical health BEFORE	3	40,6
Average physical pain value BEFORE	22,5	62,2
Average Health value in general BEFORE Average	76,8	35
vitality value BEFORE	84,4	49,4
Average value social activities BEFORE	18	59,4
Role and emotional state BEFORE	5,6	66,7
Average mental health value BEFORE	65,6	79,5
Average Values Total	341,5	462,8

Table 4: The average values for each item and the total of the averages.

Discussion

From the above data, the sample under study is mainly composed of female persons, with an average age of 41.8 years DS+- 6.8. It is interesting how the distribution of age groups and gender can be superimposed on the aforementioned study [10], probably due to the need to address aspects of illness of the disease.

Noteworthy, in our sample, the presence of an interviewee during pregnancy, given that ISTAT data published in 2015 estimate that only 12% of thalassemia women can have children, due to the high compli-
cation of infertility linked to transfusions [10].

Most of the interviewees declare to do clerical work; one declares himself unemployed, finally one freelancer. The belonging of most patients enrolled in similar types of work could be due to the need to have flexible work commitments and reduced physical effort. However, it remains a very important fact for the assessment of the QoL, the possibility of maintaining a constant but flexible working commitment to the care commitment that the disease itself requires; think of the impact of transfusions, their frequency and constant medical consultations for primary and related problems (orthopedic, cardiology, endocrinology, etc.). The fact that most of the sample has a hobby or an interest, such as reading, listening to music, light physical activity, etc., indicates an active lifestyle and that in everyday life it does not seem to be deeply affected by the disease. The major limitation to all these daily activities is determined by tiredness and a sense of fatigue caused by anemia (35%), followed by commitments related to visits to the hospital and transfusions and therapies (19%). The pains of the skeletal muscle system are also mentioned, which limit physical

activities (13%), the management of complications of the disease (8%), the general state of health (6%) and the psychological factors due to the lowering of the mood, lack of stimuli, presence of fears and worries (6%) [10]. Only one interviewee said he had to stop physical activity, probably due to the worsening of the painful symptoms and the current state of the disease, as well as to advancing age which may have caused functional limitations.

Almost all of the participants (seven out of eight) report comorbidities such as osteoporosis, hepatitis c, diabetes, cirrhosis, dysmenorrhea, cerebral ischemia, allergies, constipation, frequent in patients with thalassemia or polytransfusions, especially if prior to the discovery of the hepatitis C virus. Seven out of eight people report previous traumatic injuries, which could affect exacerbating pain symptoms and problems affecting the osteoarticular system; it would therefore be necessary to enlarge the sample to perform a stratification to limit the confounder.

The presence of joint pain is reported by the entire enrolled sample, none of them reported the use of pain relieving drugs, except one person who indicated taking Chondrotin for the treatment of osteoarthritis; also for this variable further studies and the enlargement of the sample would be necessary. At the conclusion of our study, which aimed to improve pain symptoms, important results can be highlighted: the difference between average pain referred to patients at zero time (equal to 7) and pain reported at the end of the treatment cycle, after the administration of the last OMT, (equal to 0.375) is comforting; this associated with a P value lower than 0.05 already from the second week of OMT also highlights a statistical significance of the data. Even analyzing the difference in perceived pain between the detection at time zero and that perceived after each administration of OMT it is noted that this is already wide from the first treatment (4.75; SD1.39; P Value = 0, 00025), but very clear at the end of the 5 weeks (6.63; SD 0.52; P Value = 0.00001) (tables 1 & 2). As regards the impact on the QoL (SF36 scale) [11], even if with an improvement trend, the data do not reach the expected statistical significance. However, there is a clear improvement both on the raw value and on the averages, values that could have significant changes with the increase in the sample size.

From a first evaluation, some items show an improvement in the QoL; examples are: the value of “Physical activity” which has gone from an average of 88.1 to an average of 107.8 with a difference of 17.7 points; the value of “Health in general” with an initial score of 77 and a post-surgery score of 104.5, with a difference of 27.5 points.

Even analyzing the averages for each item investigated, it is noted that these have all increased after osteopathic treatment, except for the raw value of the Mental Health item.

The analysis of the sum of the QoL values 708.8 vs 780.8 indicates an improvement, even if it does not follow the exponential trend obtained with the “pain” variable.

Finally, from the total average values this improvement is appreciated (88.6; SD 14.2625 vs 97.6; SD 15.1562 with an average increase of 9 points). Unfortunately, these data on the ANOVA test, applying the Kruskal-Wallis test, have not been confirmed the statistical significance, P Value = 0.43 (Tables 3 & 4).

Conclusion

At the conclusion of our study, we can affirm that the results obtained by us, even if coming from a small sample, highlight the usefulness and efficacy of OMT in adult patients with Thalassemia Mayor with various types of joint pain, but it could also be hypothesized that those who have benefited from osteopathic treatment for several consecutive sessions, although affected by other chronic disabling diseases, such as BTM, may also enjoy the positive effects.

This survey highlights the benefits that OMT could offer to thalassemia patients, taking advantage of a new treatment opportunity for the endpoints identified and pursued within the same specialist care center, thus opening a reflection on the possibility of including in the team also the figure of the osteopath, in line with the need to deal with the management of complex pathologies within a multidisciplinary setting. A final aspect, not of secondary importance, that emerged in this study was that the OMT included in the transfusion care protocol probably influenced the increase in the QoL of the patients, with possible implications for the management of one’s daily life, decreasing the time and the costs necessary to deal with the management of these aspects often in third structures, with consequent possible effects on work and / or family and / or social life absences.

Unfortunately, the thalassemia population on which we carried out the study was limited, and enrollment was made difficult by the inclusion and exclusion criteria, which served to limit their confounders, biases and modifiers; it would therefore be desirable to carry out the multicenter study in order to expand the sample and perform necessary stratifications. The organizational and structural difficulties did not allow to complete the study on the chosen number of 10 units, but it proved its effectiveness on the pain symptom and therefore, indirectly, also on the QoL. Unfortunately, the second area studied, that of QoL, did not achieve the same results with the expected statistical significance; however, it showed an important improvement trend that could have a more comforting result with an increase in the sample size.

At the conclusion of our study, we observe how the results are in line with other surveys carried out and published after the start of this study, aimed at people with BTM, aimed at investigating qualitative-quantitative aspects of the QoL and care of themselves.

The limitations of the study were those of the small size of the sample and the logistical difficulties, which led to having to conclude the study with a sample lower than the predetermined one, which was already very small. For the future, it may be useful to carry out a cohort study with a competing cohort to better evaluate the effectiveness of the OMT, but it needs more resources and a multicenter design to allow the evaluation of the variables studied on a larger sample.

The authors have declared that no competing interests exist.

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Title: evaluate the effectiveness of osteopathic manipulative treatment in pediatric patients undergoing appendectomy by measuring post-surgical outcomes.

Background and rational

Appendicitis is one of the most frequent pathologies ever and, among those of surgical relevance, represents the first cause of acute abdomen.
At the pediatric level, it is the most common non-traumatic pediatric emergency in children over 2 years of age.
Incidence is 0.4 in the age of less than 14 years. In children and adolescents the ratio M: F = 3: 2, after the age of 25 M = F. Early diagnosis in pediatric age is an essential condition for effective treatment.
The 'pediatric care' aimed at the observation of pediatric and postoperative pain, pays greater attention to all the possible physical, neurovegetative, mental, emotional consequences of the child linked to an experience of variable intensity, proportional to the extent of the tissue damage of acute pain ; and the effects related to the persistence of post-operative pain.

Objective of the study, to evaluate through an observational study, the effects of osteopathic manipulative therapy in the cohort of pediatric patients with appendectomy afferent to the surgery department, at the Meyer Pediatric Hospital in Florence, through the measurement of pain, recovery alvo, length of stay , antalgic pharmacological load.

Materials and methods

Inclusion criteria: patients between 5 and 17 years of age undergoing appendectomy surgery for acute appendicopathy, or recurrent abdominal pain, at the Meyer Children's Hospital.
Exclusion criteria: patients with severe comorbidities (neurological, rheumatological and osteoarticular pathologies, etc.); patients undergoing prophylactic appendectomy during other abdominal operations.

Duration of recruitment: from 01/10/2020 to 30/09/2021

Appendectomized patients will undergo two osteopathic sessions, the first within 24 hours and the second within 48 hours of surgery, the OMT will last 30 minutes.
For the extrapolation of the data, hospital software, validated tests for pain, WONG-BAKER scale for children between 3-7 years of age, and the NUMERICAL SCALE for children over 7 years were used.

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