

The EPI3-LASER study: Real-world observational evidence for homeopathy from General Physicians in France

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Abstract

Observational studies provide researchers, clinicians and patients with valuable, clinically relevant information on how a treatment performs in the real world. For homeopathy, there is a small, yet highly relevant, body of such evidence supporting the usefulness of homeopathic treatment, especially in Europe. Here we summarise the results of a large-scale population-based observational study in France, assessing homeopathy provided in primary care. The EPI3-LASER study assessed 8559 patients, treated by 825 general physicians (GPs), for musculoskeletal disorders; sleep, anxiety and depressive disorders; and upper respiratory tract infections. Patients treated by GPs certified in homeopathy were found to have similar clinical outcomes to patients using conventional medicine alone, but with reduced use of conventional drugs and at 20% lower overall cost. Use of gold standard scientific methodology ensures that these results – identifying potential benefits of homeopathy as part of an integrated healthcare model – are reliable, generalisable and most importantly, clinically meaningful.

Introduction

To patients, clinicians and decision makers, what matters most is not necessarily how well a treatment performs under the artificial conditions of a randomised controlled trial (RCT), but rather how much clinical benefit a treatment provides when used by patients in the real world. Observational studies allow researchers to answer this question by collecting and analysing data from everyday clinical practice, without any interference with patients' usual care.

Observational studies performed in France, Germany, Italy and the UK have provided valuable insights into the impact of homeopathic treatment – consistently showing patient benefit, often in chronic, difficult to treat conditions.¹ Thus, there is a small, yet highly relevant body of evidence supporting the real-world value of homeopathy.

A key contribution to this evidence base comes from a nationwide study assessing the real-world impact of homeopathy in France: the "etude epidemiologique de l'impact de sante public sur 3 groupes de pathologies", or "EPI3". This programme of work was conducted by LASER, an independent UK-based research company, giving rise to the formal name "EPI3-LASER study" resulting in twelve publications to date (2011-2018).²⁻¹³

The EPI3-LASER study

Homeopathy in France is readily available in pharmacies, practiced exclusively by doctors and is partly reimbursed by National Health Insurance. To assess the impact of homeopathy in primary care in France, a population-based observational study of a representative sample of GPs and their patients was conducted over the course of a year. Clinical data were collected from 825 GPs and 8559 patients from March 2007 to July 2008.²

Participating GPs were classified according to their main prescribing approach: only conventional medicine (GP-CM), regularly prescribing homeopathy within a mixed practice (GP-Mx) or being certified homeopathic GPs (GP-Ho). Although there was no statistically significant difference in socio-demographics of patients between each group, patients

seeking treatment by GP-Ho were more likely to be female; more highly educated; with a healthier lifestyle (lower body mass index, smoking and alcohol use) and a more positive attitude to complementary and alternative medicine.⁷

Musculoskeletal diseases were the most commonly treated conditions and had the most pronounced effect on the physical health of patients. Cardiovascular diseases and psychological disorders were the next most frequently seen conditions.² For patients consulting GP-Ho, chronic conditions such as back pain, anxiety disorders and dermatological problems were most prominent.⁷

Three specific patient cohorts were followed: Musculoskeletal Disorders (MSD); Sleep, Anxiety and Depressive Disorders (SADD) and Upper Respiratory Tract Infections (URTIs). These clinical categories were selected due to their prevalence and high burden in primary care, but also as key areas where a reduction in prescription drug use is sorely needed.

Musculoskeletal disorders cohort

In the MSD cohort, 1692 eligible patients were followed for 12 months, comparing groups treated by GP-Ho, GP-CM or GP-Mx. Patient characteristics did not differ between groups except for chronicity of MSDs, which was higher in the GP-Ho group compared to both the GP-CM and GP-Mx groups.³

Clinical progression, drug use, side effects and loss of therapeutic opportunity were assessed when entering the study, then after 1, 3 and 12 months. Patients with chronic MSD in the GP-Ho group showed a similar clinical progression compared to those in the GP-CM group, used fewer analgesics, fewer non-steroidal anti-inflammatory drugs (NSAID) and had fewer NSAID-related side effects. Specifically, analgesic and NSAID use was almost halved in the GP-Ho group compared to the GP-CM group (OR=0.40, 95%CI: 0.20 to 0.82; OR=0.56, 95%CI: 0.35 to 0.90); no statistically significant difference was found between the GP-CM and GP-Mx groups (OR=0.54, 95%CI: 0.27 to 1.08; OR=0.81, 95% CI: 0.59 to 1.15).⁵ Additionally, the changes seen in scores for back pain, and arm and leg disability over twelve months were identical for all groups ($p > 0.05$).

Clinical results and drug use in patients treated by homeopathic GPs (GP-Ho) compared to patients treated by conventional GPs (GP-CM)

| | CLINICAL RESULTS | ANALGESICS | NSAIDS | PSYCHOTROPICS | BENZODIAZEPINES | ANTIBIOTICS | ANTIPYRETICS/ ANTI-INFLAMMATORIES |
|---|------------------|------------|--------|---------------|-----------------|-------------|--------------------------------------|
| Musculoskeletal disorders | | | | | | | |
| Total (N=1692) | = | ↓ | ↓ | | | | |
| ≥70 years (N=146) | = | = | ↓ | | | | |
| Sleep, anxiety and depressive disorders (SADD) | | | | | | | |
| Total (N=1572) | | | | ↓ | | | |
| Sleep disorders (N=346) | = | | | ↓ | | | |
| Anxiety & depression (N=710) | ↑ | | | ↓ | | | |
| ↳ ≥65 years (N=87) | ↑ | | | ↓ | ↓ | | |
| Upper respiratory tract infections (URTI) | | | | | | | |
| Total (N=518) | = | | | | | ↓ | ↓ |
| = similar ↑ superior clinical improvement (p<0.05) ↓ reduced use (p<0.05) | | | | | | | |

A similar result was seen for a sub-group of 146 elderly patients (≥ 70 years of age) – a group more likely to suffer musculoskeletal pain and be prescribed analgesics than the general adult population. Clinical improvement and analgesic use was the same regardless of the type of GP consulted, but importantly, patients treated by GP-Ho achieved these similar results with reduced use of NSAIDs (GP-CM compared to GP-Ho OR=3.71, 95% CI: 1.12 to 12.3; GP-Mx compared to GP-Ho OR=2.52, 95% CI: 1.05 to 6.05).⁸

Sleep, anxiety and depressive disorders cohort

In the SADD cohort of 1572 patients, psychotropic drugs were more likely to be prescribed by GP-CM (64%), than GP-Mx (55.4%) and GP-Ho (31.2%). All treatment groups had similar SADD severity, comorbidities and quality of life, suggesting that complementary treatments could reduce the risk of exposure to addictive psychotropic drugs without loss of therapeutic opportunity.⁶

Considering only sleep disorders (346 patients), those treated by GP-Ho were significantly less likely to use psychotropic drugs compared to the GP-CM group (OR=0.25, 95% CI: 0.14 to 0.42). Patients in the GP-Mx group also used fewer psychotropic drugs, but the result was not statistically significant (OR=0.67, 95% CI: 0.39 to 1.16). Rates of clinical improvement in sleep quality did not differ between groups, showing no loss of therapeutic opportunity with reduction of psychotropic drugs and usage of homeopathy.¹¹

710 patients with anxiety and depression were assessed for drug use and clinical progression. Patients in the GP-Ho and GP-Mx groups were less likely to use psychotropic drugs compared to GP-CM (OR=0.29, 95% CI: 0.19 to 0.44 and OR=0.62, 0.94 respectively), and clinical improvement was marginally superior for the GP-Ho group.¹²

In a small sub-group of 87 elderly patients (≥65 yrs) with anxiety and depressive disorders, the GP-Ho group were significantly more likely to benefit from treatment than the GP-CM group (OR=10.38, 95% CI: 1.33 to 81.07), used fewer psychotropic drugs (OR=22.31, 95% CI: 2.20 to 226.31) and less benzodiazepine (OR=60.63, 95% CI: 5.75 to 639.5).¹³

Upper respiratory tract infections (URTIs) cohort

The third main cohort of patients followed 518 adults and children with URTIs, assessing drug use: patients in the GP-Ho group showed a significantly lower consumption of antibiotics (OR=0.43, 95% CI: 0.27 to 0.68) and antipyretic/anti-inflammatory drugs (OR=0.54, 95% CI: 0.38 to 0.76), with similar clinical results compared to the GP-CM group. No difference was seen between the GP-Mx and GP-CM groups.⁹

Economic impact

In addition to thorough assessment of the clinical impact of consulting GP-Ho, the EPI3-LASER study collected data on the economic impact on the French Social Security reimbursement system, as well as the out-of-pocket costs to patients and their supplementary health insurers.¹⁰

In the GP-Ho group, the cost of treatment was greater out-of-pocket for patients and their insurers due to higher consultation tariffs, but was cheaper for the French Social Security due to lower prescription costs. These differences balanced out so overall, when all direct costs were taken together, patients treated by GP-Ho cost 20% less than patients treated by GP-CM, while GP-Mx were comparable to the GP-CM group. This cost assessment did not include indirect or subsequent costs due to hospital referrals (noted to be few), medical tests, sick days or treatment of side effects, but rather focused solely on the direct cost incurred on the day patients saw their GP.¹⁰

Critical assessment

As the EPI3 study is an observational study, it does not directly compare efficacy of conventional drugs with homeopathy, or demonstrate cause and effect (that requires the artificially controlled conditions of an RCT). Observational studies are necessarily selective and unblinded, (EPI3 patients chose which GP to visit and knew what treatment they received). However, this does not mean such studies have less value than RCTs. There are many research methods and data handling processes available to mitigate 'uncontrollable' aspects of observational studies (e.g. multivariate regression and adjustment for baseline differences with propensity scores), all of which were used in the EPI3-LASER study, making the findings robust.

Indeed, an independent pharmaceutical consultant recently assessed the scientific approach and analytical methods used in the EPI3 study and found them to be exemplary, in full accordance with gold standard observational studies.¹⁴ Thus, the validity of the EPI3 findings has been fully verified: the results are reliable, generalisable to the French population and most importantly, clinically meaningful.

Conclusion

The take home message from the EPI3-LASER study is that patients in France who consult a homeopathic GP for some of the most prevalent and burdensome conditions in general practice, cost 20% less, get better at the same rate, and use fewer drugs compared to patients consulting GPs prescribing conventional medicine only. These findings were obtained using the highest methodological standards and are generalisable to other populations.¹⁴ As the issue of polypharmacy (use of multiple drugs in a single patient) is a global problem, particularly in the elderly population¹⁵ the EPI3-LASER study is a significant piece of evidence, adding to that from other European countries, identifying the potential beneficial impact of homeopathy when used within an integrated healthcare model.

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