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AN OPEN LABEL PROSPECTIVE STUDY TO EXPLORE EFFICACY OF IPECACUANHA IN CASES OF BRONCHIAL ASTHMA

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ABSTRACT:

Bronchial Asthma is a chronic inflammatory illness characterized by periods of shortness of breath, wheezing, coughing, chest tightness, and other symptoms produced by bronchial hyper responsiveness and fluctuating air flow blockage that can be reversed spontaneously or with medication. The World Health Organization recognizes bronchial asthma as a major health problem. According to the most recent Global Burden of Diseases (GBD) study, 339.4 million persons worldwide have a high prevalence of asthma. Asthma is ranked 16th in the world for years lived with disability and 28th in terms of disease burden.

The prevalence of asthma is higher in industrialized countries than in developing countries. An estimated 15-20 million people in India suffer from asthma. In India, its incidence is around 2%. It is one of the causes of poor quality of life, with reduced capacity to complete daily activities (85%), physical activity limitation (69%), loss of productivity at work (73%) or education (64%), and restrictions on leisure and lifestyle (78%). Homeopathy is a discipline founded on the laws of similarity, which means that it treats diseases using medications that produce comparable symptoms in healthy people. Homeopathy treats the individual as a whole. In acute attacks as well as for chronic conditions there is group of medicines like Natrum Muriaticum, Natrum Sulphuricum, Bromium, Antimonium crude and Ipecacuanha.

Keywords: Asthma, Homoeopathy, Weakness, Breathlessness, Cough, Restlessness, Pyrexia, Ipecacuanha.

Introduction:

Respiratory disorders are divided in broadly under two classes whilst upper and lower respiratory disorders. URTIs are caused by viruses or bacteria. It affects the upper airways (nose, throat). In people with asthma, these infections can lead to inflammation and narrowing of the airways, making breathing difficult. Common symptoms of URTIs include runny nose, sore throat, cough, and sometimes fever.

Asthma symptoms include wheezing, shortness of breath, chest tightness, and coughing. There is heightened sensitivity for irritants like smoke, pollen, and cold air can induce inflammation in the lungs. Asthma causes inflammation in the lungs, which leads to constriction of the breathing passageways. It is a complex disease that involves both hereditary and environmental variables. Several risk factors that contribute to asthma have been discovered. These should be distinguished from triggers, which are environmental conditions that exacerbate asthma in a patient with established disease. Endogenous risk factors include genetic predisposition, gender, atopy and ethnicity, while exogenous risk factors include allergens, occupational sensitizers, smoking, infection, obesity, and nutritional variables, among others.

Homoeopathic system evolved a drug regimen of using acute remedies for acute attack and constitutional deep acting remedies to prevent recurrence.

Among the disease classification of Master, asthma comes under true natural chronic disease caused by the chronic miasm. It also excited by a number of precipitating and maintaining factors and influenced by genetic family history. Asthma can be considered as intermittent disease as it recurs at regular intervals in some patients. Similarly, it can be regarded as alternating disease as they sometimes alternate with skin diseases.

Asthma can be caused by psora, syphilis, sycosis or the combinations of these. In 80th aphorism, Master says 'the monstrous internal chronic miasm – the psora, the real fundamental cause and producer of all other numerous diseases including asthma and ulceration of lungs etc.

⇒ **TYPES:**

i. **Intrinsic /idiosyncratic:**

→ Occurs in nonallergic patients due to non-immunologic stimuli such as infections, exercise, emotional upset, irritating inhalants and cold air etc.

→ The asthma attacks are severe, and prognosis is less favourable.

ii. Extrinsic/allergic/atopic:

→ Occurs because of sensitization. There is a positive family history of allergic disease.

→ It is precipitated by allergens and patient might present with classic 'atopic triad' of allergic rhinitis, wheezing, and eczema. Prognosis is good.

Many patients have features of both types.

Table 1: Clinical classification of asthma[5]

	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Day time Symptoms	< 2/week	> 2/week but <1/day	Daily	Continuous &frequent
Night time Symptoms	< 2/month	> 2/month	> 1/week	More frequent
Variation in PEFR	< 20%	20-30%	> 30%	> 30%

⇒ **FACTORS PRECIPITATING ATTACK OF ASTHMA:[5]**

→ **Respiratory infections:** Especially viral, are the most common stimuli to cause asthma attacks. RSV in young children and rhinoviruses in adults are the major causes.

→ **Pharmacologic stimuli:** Very important in some cases, and the most common etiologic agents associated with asthma exacerbation are aspirin, β-blockers, and colouring agents such as tartrazine.

→ **Environmental allergens:** Like house dust mites, animal allergens (especially cat and dog), cockroach allergens, and fungi are most commonly reported.

→ **Exercise:** Exercise can trigger an early asthmatic response. Factors that contribute to *Exercise Induced Asthma*(EIA) symptoms include the following:

- Exposure to cold or dry air
- Duration and intensity of exercise
- Coexisting respiratory infection

→ **Emotional factors:** In some individuals, emotional upsets clearly aggravate asthma.

→ **Gastroesophageal reflux (GER):** The presence of acid in the distal oesophagus, mediated via vagal or other neural reflexes, can significantly increase airway resistance and airway reactivity.

→ **Aspirin triad/Samter's triad:** Some patients suffer from *aspirin allergy*, *nasal polyps&asthma*, a condition known as the "*aspirin triad"*. Aspirin allergy can develop later in life, even when previously well tolerated. It usually starts with perennial vasomotor rhinitis; later, asthma appears that occurs with minimal ingestion of aspirin. There is significant cross reactivity between aspirin and NSAIDs. Patients can be desensitized by daily administration of aspirin. Over secretion of leukotrienes and their activation of mast cell is the mechanism by which aspirin causes this triad and that's why leukotriene inhibitor is so effective in its treatment.

→ **Nocturnal asthma:** During night pulmonary functions are at their lowest level because circulating blood levels of epinephrine and cortisol – which protect the body against asthma – are at their lowest levels.

→ **Genetics:**There is a strong association of the ADAM 33 gene with asthma & bronchial hyperresponsiveness.[6]

→ **Physical Factors:** Cold air & hyperventilation may trigger asthma through the same mechanisms as exercise. Laughter may also be a trigger. Many patients report worsening of asthma in hot weather and when the weather changes. Some asthmatics become worse when exposed to strong smells or perfumes, but the mechanism of this response is uncertain.[7]

→ **Food & Diet:** Certain food additives may trigger asthma. Metabisulfite, which is used as a food preservative, may trigger asthma through the release of sulphur dioxide gas in the stomach. Tartrazine, a yellow food-colouring agent, was believed to be a trigger for asthma, but there is little convincing evidence for this.[7]

→ **Air Pollution:** Increased ambient levels of sulphur dioxide, ozone, diesel particulates and nitrogen oxides are associated with increased asthma symptoms.[7]

→ **Occupational Factors:** Several substances found in the workplace may act as sensitizing agents, as discussed above, but may also act as triggers of asthma symptoms. Occupational asthma is characteristically associated with symptoms at work with relief on weekends and holidays. If removed from exposure within the first 6 months of symptoms, there is usually complete recovery. More persistent symptoms

lead to irreversible airway changes, and, thus, early detection and avoidance are important.[7]

→ **Obesity:** Asthma occurs more frequently in obese people (BMI >30 kg/m2) and is often more difficult to control. Although mechanical factors may contribute, it may also be linked to the pro-inflammatory adipokines & reduced anti-inflammatory adipokines that are released from fat cells.[7]

→ **Hormones:** Some women show premenstrual worsening of asthma, which can occasionally be very severe. The mechanisms are not completely understood, but are related to a fall in progesterone and in severe cases may be improved by treatment with high doses of progesterone or gonadotropin-releasing factors. Thyrotoxicosis and hypothyroidism can both worsen asthma, although the mechanisms are uncertain.[7]

→ **Stress:** Many asthmatics report worsening of symptoms with stress. Psychological factors can induce bronchoconstriction through cholinergic reflex pathways. Paradoxically, very severe stress such as bereavement usually does not worsen, and may even improve, asthma symptoms.[7]

→ **Other Factors:** Several other factors have been implicated in the etiology of asthma, including lower maternal age, duration of breastfeeding, prematurity & low birthweight, and inactivity, but are unlikely to contribute to the recent global increase in asthma prevalence.[7]

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→ **Food & Diet:** There is little evidence that allergic reactions to food lead to increased asthma symptoms, despite the belief of many patients that their symptoms are triggered by particular food constituents. Exclusion diets are usually unsuccessful at reducing the frequency of episodes. Some foods such as shellfish and nuts may induce anaphylactic reactions that may include wheezing. Patients with aspirin induced asthma may benefit from a salicylate-free diet, but these are difficult to maintain. Certain food additives may trigger asthma. Metabisulfite, which is used as a food preservative, may trigger asthma through the release of sulphur dioxide gas in the stomach. Tartrazine, a yellow food-colouring agent, was believed to be a trigger for asthma, but there is little convincing evidence for this.[7]

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⇒ **MANAGEMENT OF ASTHMA[9]**

Patient Education

It is aimed to enable asthmatic patient to treat himself under guidance of his doctor. It is achieved by proper education of the patient. Patient education is as important as drug treatment. Every patient with asthma should learn to take medicines regularly, correctly and understand the difference between relieving and preventive medicines. Identification and avoidance of risk factors and triggers involved in asthma are also important components of patient education. Monitor in the severity of the disease by symptom score or peak-flow meter, action plans for a situation like exercise-induced and acute attack, and misconception about the disease should also be addressed.

Identify &reduce exposure to risk factors

Asthma exacerbation can be caused by a variety of trigger factors. Early identification of a trigger factor and preventing its exposure improves asthma control and reduces requirement of medicines.

Assess, monitor &treat asthma

Asthma control is assessed and then patient is treated to achievethe control. Once adequate control is achieved, the patient is monitored regularly to maintain the control.

Manage exacerbation

The aim of this treatment is to relieve broncho-spasm and hypoxia as quickly as possible. A future plan is made to prevent recurrence of episodes of exacerbation.

Special Situation

At times, asthma management requires attention to special situations such as allergic rhinitis, pregnancy, aspirin sensitivity, occupational compulsions, and gastro-esophageal reflux.

⇒ **COMPLICATION[4]**

→ Though mortality is low, severe asthma may result in respiratory failure and death even in the most unexpected situation.

→ Other complications include frequent respiratory infections, pulmonary collapse due to obstruction by viscid secretions, pneumothorax, mediastinal emphysema &cough fractures (fractures of ribs due to violent coughing).

→ Children with asthma may show retardation of growth, especially if treated with systemic corticosteroids on a long-term basis.

→ Longstanding bronchial asthma, punctuated with frequent respiratory infections may lead on to emphysema & chronic cor pulmonale.

Asthma Control Test

→ The Asthma Control Test (ACT) is developed as a screening tool to address the need for a simple, rapidly completed assessment tool in clinical practice.[10]

→ The ACT is a validated, patient-completed measure of asthma control comprising five questions that assess activity limitation, shortness of breath, night-time symptoms, use of rescue medication, and patient overall rating of asthma control over the previous four weeks.[10]

→ The Asthma Control Test (ACT) is a 5-item self-administered survey. Each question is scored from 1 to 5, with the total score being the sum of all questions. The range of the total score can be from 5 to 25.

→ There will be three categories as very poorly controlled patients (less than 16), poorly controlled patients (16 - 19) &well controlled patients (20-25). The minimum clinically important difference is 3 points[11].

⇒ **Description:**

→ There is relationships between ACT score with co-relation to patient's mode of living. By aiding our understanding of how ACT score is reflective of the different aspects of patients' asthma experience, this review provides support for its use as a viable measure for other outcomes.

→ Various studies showed that the power have been given in some of the evaluated studies, either by being insufficiently powered to evaluate the relationships between ACT score and the outcomes of the clinical interest. ACT will only assess clinical symptoms of Asthma and it is not significant to the HRQoL(Health Related Quality of Life).

→ With respect to future work, the exploratory setup of this research provides a characterization of the topics on which scientific data regarding the ACT are present or absent. As such, the current report provides a starting point to explore and corroborate these findings in future research initiatives on the value of ACT scores in real-world clinical settings. More studies evaluating relationships between ACT score and general HRQoL with differing levels of asthma severity.

⇒ **ACT &Homoeopathic perspective:**

→ Using this ACT, physician can assess the individuals as a whole, not only the clinical symptoms of Asthma.

→ This will also help not only to improve clinical symptoms of Asthma but gives the healthy life to the patients.

IPECACUANHA

➢ **ACCORDING TO BOERICKE MATERIA MEDICA:-**

The chief action is on the ramifications of the pneumo-gastric nerve, producing spasmodic irritation in chest and stomach. Morphia habit. The principal feature of Ipecacuanha is its *persistent nausea* & vomiting, which form the chief guiding symptoms. Indicated after indigestible food, raisins, cakes, etc. Especially indicated in fat children and adults, who are feeble and catch cold in relaxing atmosphere; warm, moist weather. Spasmodic affections. Hæmorrhages*bright-red*and*profuse*.

Respiratory.--Dyspnœa; constant*constriction in chest*. Asthma. Yearly attacks of difficult shortness of breathing. Continued sneezing; coryza; wheezing cough.*Cough incessant and violent, with every breath*. Chest seems full of phlegm, but does not yield to coughing. Bubbling rales. Suffocative cough; child becomes stiff, and blue in the face. Whooping-cough, with nosebleed, and from mouth. Bleeding from lungs,*with nausea*; feeling of constriction; rattling cough. Croup. Hæmoptysis from slightest exertion (*Millef*). *Hoarseness*, especially at end of a cold. Complete aphonia.

- **DR. J. H. CLARKE SAYS:-**

Respiratory Organs:-

Cough, especially at night, with painful shocks in the head and stomach, and with loathing, retching, and vomiting. Cough catching the breath, even to suffocation, during the attacks the child gets quite stiff, its face blue. It is excited by a contractive tickling sensation extending from upper part of larynx to lowest part of bronchial tubes, worse on walking in cold air, on retiring, in morning and evening, on taking a deep breath. Accompanied by cold, as if the navel would be torn out, pains in abdomen like strangury, heat in head and face. The cough causes vomiting without nausea. Rattling noise in the bronchial tubes when drawing breath. Dry cough, excited by a contractive tickling in the larynx (particularly in the upper part), extending to the extremity of the bronchia, especially when lying on left side. Cough, which resembles whooping-cough, with bleeding from the nose and mouth, and vomiting of food. Spasmodic cough, dry shaking, with fits of suffocation, stiffness of the body, and bluish face. Cough as from vapor of sulphur, with expectoration of blood with mucus in the morning. Suffocative cough in the evening, continuous cough with perspiration on the forehead, shocks in the head, retching and vomiting.

- Anxious and short respiration. Quick, anxious breathing. The breath smells fetid. Suffocative attacks in the room. More in the open air. Whooping-cough, every fresh attack sets in with a long-drawn, difficult howling, sighing inspiration. Spasmodic asthma, with contraction of the larynx.

- **Chest.**:-

Oppression of the chest, and shortness of breath, as if dust had been inhaled. Loss of breath on the least movement. Spasms in the chest. Palpitation of the heart. Red itching spots on the chest, with burning after scratching.

- **Dr. Jahr says:-**

Cough, particularly at night, with painful shocks in the head and stomach, with loathing, choking and vomiting. - Dry cough, from a contracting tickling in the larynx, extending to the deepest end of the bronchia.:- Dry, shaking spasmodic cough, with obstruction of the breath, even to suffocation. - Suffocating cough, with stiffness of the body and blueness of the face.- Whooping-cough. Respiration anxious and hasty. - Spasmodic tightness of the chest, with contraction in the throat and asthmatic breathing. - Sighing respiration. - Oppression of the chest and short breath, as from much dust. - Asthma Millari.

- **DR. H. C. ALLEN SAYS:-**

Cough: dry spasmodic, constricted, asthmatic. Difficult breathing from least exercise; violent dyspnoea, with wheezing and anxiety about the stomach.

Whooping-cough: child loses breath, turns pale, stiff and blue; strangling, with gagging and vomiting of mucus; bleeding from nose or mouth ([Ind.]). Cough, with rattling of mucus in bronchi when inspiring (Ant. t.); threatened suffocation from mucus.

DR. J. T. KENT SAYS:-

Chest:- The chest complaints ofIpecac. are interesting.Ipecac. is especially the infant's friend and is commonly indicated in the bronchitis of infancy. The usual bad cold that ends in chest trouble in infants is a bronchitis. It is very seldom that an infant gets a true pneumonia, it is generally a bronchitis with coarse rattling. The child coughs, gags and suffocates, and there is coarse rattling which can be heard throughout the room, and the trouble has come on pretty rapidly. The child is pale, looks dreadfully sick, and sometimes looks very anxious. The nose is drawn in as if dangerously ill, and the breathing is such as appears in a dangerous case. In the old books, the pneumonia of infancy had a distinct and separate description, and the typical symptoms were those ofIpecac.

MATERIAL & METHODOLOGY

MATERIALS:

Source of collection of data:

The subjects required for conducting the study on Bronchial Asthma Will be selected from the below mentioned centres of Rajkot Homoeopathic Medical College (affiliated to Parul University), Rajkot, Gujarat.

1. "Sainath Homoeopathic Hospital, OPD, Rajkot."
2. Peripheral Regular camps carried out by Sainath Homoeopathic Hospital, Rajkot.

Materials to be used during the research:-

1. CCRH designed chronic case proforma as well as acute case proforma.
2. IPECACUANHA remedy will be used in various potencies from seal packed bottles from reputed pharmaceutical company. (according to guidelines given by master Hahnemann in organon of medicine aphorism 246-272)

Number of cases:A total number of 50 cases will be screened after fulfilling the inclusion as well as exclusion criteria.

Duration of study: follow up of the cases will be followed from JULY 2019 – JUNE2021

Criteria for the diagnosis of disease: The diagnosis made on the basis of strong clinical presentation, examination findings as well as investigations.

Selection of Samples: Randomized sampling. Sample size will be determined by using the following formula.

$$\textbf{Sample size}, S = \frac{Z^2 \times P \times (1 - P)}{e^2}$$

Where Z = Z score = 1.96 considering confidence level is 95%,

P = Prevalence rate

e = margin of error = 5% so, e = 5/100 = 0.05

I. **Inclusion Criteria:** Criteria for selection of the patient for intended work.

a) Diagnostic criteria were mainly based on clinical history, presentation and examination findings.

b) Diagnosed case under treatment not controlled, want to shift to Homoeopathy.

c) Already taken other treatment but not cured or having relapses again.

d) Age – Between 15 - 45 years.

e) Sex-Both the sexes

f) Patients of all the socio-economic status

II. **Exclusion Criteria:**

a) As given by Master Hahnemann in classification of diseases i.e. Surgical disease: include injuries occurring to body from without. The treatment of such cases are relegated to surgery {Aphorism: 186}.

b) Patients with complications of Bronchial Asthma and who required hospitalization.

c) Age- <15 and >45 years.

d) Patient with malignant condition and deep pathological changes

METHODOLOGY:

I. Type of Study: -Open Label Prospective Studywas conducted.

The study has been performed by following ways:

a. Case taking: The data will be collected from patients by interviewing them and from clinical examination according to guidelines given by Dr. Samuel Hahnemann in Organon of Medicine- 5th edition (Aphorism from 83-104)

b. Once the data will be recorded, it will be processed as per the guidelines adapted in the specialized case record which is designed according to the norms of CCRH.

c. The Characteristics symptoms, PQRS symptoms, general symptoms and particular symptoms of the patient will be recorded.

d. IPECACUANHA will be dispensed for each case after referring Homoeopathic MateriaMedica, Therapeutics and various repertories according to the availability and presentation of symptoms. (Aphorism: 147)

e. Measurement of Susceptibility and Selection of Potency: - Susceptibility will be measured on the basis of age of patient, pace & type of asthma, personality of patient, etc and henceforth potency selection will be depending upon miasmatic analysis & susceptibility of patient.

Protocol Plan B:

Cases will be analysed and evaluated in a systemic manner and in accordance with totality of symptoms **a constitutional medicine can be prescribed but since therapeutically IPECACUANHA has been a well-known and well used remedy for the above cases** the remedy IPECACUANHA will be used in the different potencies and doses as per need.

II. Assessment of Effectiveness:

After following up the cases weekly or fortnightly, assessment of the effectiveness of the treatment will be done based on the following criteria:

a. Clinical assessment will be based on disappearance or relief of symptoms like dyspnoea, mucous secretion, wheezing, breathlessness and associated symptoms like alteration of taste, fatigue etc as well as assessing the improvement in the physical generals such as thirst, sleep, diet etc. Along with the above parameters Peak exploratory flow rate, and frequency of use of Bronchodilator drugs will be taken into consideration to assess the effectiveness.

b. For an effective evaluation and assessment of disease, intensity of symptoms & findings will be graded in every patient based on their presentation observed during case taking.After completion of the study, the post treatment disease scores will be compared with the pre-treatment disease scores and statistically evaluated.

c. Responses are been divided into 4 criteria:

1. **Significant improvement:** Disappearance of presentation with general wellbeing of patient without relapse.
2. **Improved:** Recovery in present complaints
3. **Status quo:** Not improved
4. **Worse:** worsening of the present complaints
5. **Drop out:** Improved or not improved, eventually left the treatment.

d. CLINICAL ASSESSMENT SCORE

CLINICAL ASSESSMENT SCORE

Criteria for Assessment	Scores
Cough	**Excessive – 4** **Moderate – 3** **Mild – 2**

	Occasional – 1 **Absent – 0**
Wheezing	**Excessive – 4** **Moderate – 3** **Mild – 2** **Occasional – 1** **Absent – 0**
Dyspnea	**Excessive – 4** **Moderate – 3** **Mild – 2** **Occasional – 1** **Absent – 0**
Use of Bronchodilator drugs	**Daily use Bd – 4** **Daily use Od – 3** **Alternate day – 2** **Once in week – 1** **No use – 0**

OBSERVATIONS & RESULT

The present research work was a hospital based analytical, Prospective study which was conducted in the Sainath Homoeopathic Hospital, Rajkot . The study period was from June 2019 to July 2021. A total of 50 newly Asthma patients were included in the study. In this open label study, 43 patients were selected. 07 patients were dropped-out due to irregular or missed follow-up. Observations & statistical analysis was done on 43 patients as per protocol. Following observations were assessed and presented in the form of tables & figures:

Observations were analysed as under:

Age Incidence of Asthma

In the present study, it was observed that out of 43 patients, maximum incidence was observed in the age group of 15-25 years ,(n=38; 88.37%), minimum incidence was observed in the age group of 36-45 years.

SEX Incidence of Asthma

The study showed the maximum sex incidence out of 43 patients, was in males (n=23; 53.49%) and in females (n= 20; 46.51%).

Presenting Complaints of Asthma

In the present study, Presenting Complaints are weakness (n=30; 69.77%), Breathlessness (n=43; 100%), Cough (n=40; 93.02%), Restlessness (n=35; 81.40%),Pyrexia (n=30; 69.77%).

Controlled Status according to Asthma control Test Score

As shown in the above Table, maximum patients showed Well Controlled (n=16,37.21%), Poorly Controlled (n= 10,23.26%), Very Poorly Controlled (n = 5,11.63%), followed by status quo (n=6; 13.95%) and worse (n=6; 13.95%).

Result of the study

As shown in the above Table, maximum patients showed Significant Improvement (n=19; 44.19%), Improved (n= 12; 27.91%) followed by status quo (n=6; 13.95%) &worse (n=6; 13.95%).

CONCLUSION

Studies have shown that homoeopathic treatment for respiratory diseases was associated with a significant reduction in the use and costs of conventional drugs (Rossi et al., 2009) Homeopathy has remained one of the most widespread forms of complementary medicine and is used to treat asthma. The prevalence estimates of complementary therapy use for asthma vary widely, from 6 to 70% .

The above case it is observed that Bronchial Asthma could be successfully managed with help of Homoeopathy. Asthma is the most common respiratory disorder which should be suspected in patients with recurrent cough, wheeze, chest tightness and dyspnea, and should be confirmed using objective measures of lung function. Allergy testing is highly recommended to identify its possible triggers. All asthmatics should have regular follow up visits during which criteria for asthma control, adherence to therapy (conventional or homoeopathic) and proper inhaler technique, if in use, should be revived.

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