Incidence of spinal palpatory findings: A review

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Epidemiologic studies of the incidence of somatic dysfunction in a normal or asymptomatic population are needed to evaluate somatic dysfunction as an etiologic factor or as a reflection of disease. Nine studies of the incidence of spinal palpatory findings are reviewed to see if there are commonalities in the patterns of somatic dysfunction, and whether insights into the nature of spinal dysfunction can be gained by an overview of these studies.

Interrater reliability studies account for data reported by Denslow,¹ McConnell,² Kappler,³ and Beal.⁴ Heilig⁵ recorded the spinal findings in 200 cases selected from his family practice. Cox⁶ and Beal⁷ reported on the incidence of spinal palpatory findings in subjects examined for coronary artery disease, and Miller⁸ and Beal⁹ plotted the incidence of spinal palpatory findings in patients with pulmonary disease. These investigators examined the subjects either in the hospital or an ambulatory clinical setting.

Denslow¹ reported on the results of an interexaminer study of two observers who examined 61 subjects independently without knowledge of the history or clinical findings, and recorded the incidence of tissue texture abnormality at the spinous processes. The areas of highest incidence of lesion were the upper cervical region, the midthoracic area, and the lumbosacral area (Fig 1).

McConnell and associates² reported on an interrater reliability study by six osteopathic physicians. Three physicians examined 21 patients independently. Only the primary examiner knew each patient's history. Each physician conducted a neuromusculoskeletal examination using his own customary examination method. Spinal segments were rated on a scale of 0 to 3 for the clinical signifi-

cance of the presence of somatic dysfunction. A composite chart of the six examiners' findings for the 21 patients weighted by the scaled subjective evaluation for significance shows peak incidence of findings at the occipital area, the cervicothoracic junction, the thoracolumbar junction, and the lumbosacral spine (Fig 2).

Kappler³ reported on the results of a double-blind study of the incidence of spinal palpatory findings in 837 examinations performed by experienced examiners and students. The students and experienced examiners conducted their examinations independently without knowledge of the history or physical findings. In addition, the attending physician was blinded as to the results of the structural examination. Findings were based on inspection, motion testing, and palpation. A composite chart of the incidence of spinal findings was plotted for both right and left sides. However, if the graph is altered to show only the greater incidence of either right- or left-sided findings, then peak incidents are observed at the upper cervical spine, the upper thoracic spine, the thoracolumbar spine, and the lumbosacral spine. There is a higher incidence of findings throughout the thoracic spine area (Fig 3).

Another interexaminer study reported by Beal and Dvorak⁴ was conducted by two physicians—one an osteopathic physician and the other a physician who is a teacher in the Swiss School of Manual Medicine. The physicians each examined 50 patients independently without knowledge of the history or physical findings. The patients were selected on the basis of a diagnosis of cardiovascular disease, pulmonary disease, gastrointestinal disease, or musculoskeletal injury or disease. Spinal findings were rated from 0 to 3 for significance. A plotted composite graph shows peak incidences of spinal findings for the osteopathic physician (solid line) at the upper cervical spine cervicothoracic

Fig 1. Incidence of palpatory findings in blind ambulatory study in 61 subjects by Denslow,¹ using tissue texture at the spinous process.

Fig 2. Incidence of palpatory findings in blind ambulatory study in 21 patients by McConnell and associates,² using tissue texture, position, and joint motion (scaled for significance from 0 to 3).

Fig 3. Incidence of palpatory findings in double-blind hospital study (837 examinations) by Kappler,³ using inspection, motion testing, and palpation.

Fig 4. Incidence of palpatory findings in blind hospital study in 50 patients by Beal and Dvorak,⁴ using tissue texture, position, and joint motion (scaled for significance from 0 to 3). Solid line represents osteopathic physician's findings; broken line, those of physician-teacher in Swiss School of Manual Medicine. (Reprinted with permission.)

area, thoracolumbar area, and lumbosacral spine (Fig 4).

Heilig⁵ examined 200 patients in his practice who had a low back complaint or a postural alteration affecting the low back. Lesion sites were selected on the basis of altered vertebral mechanics, restricted motion, and point tenderness. The data were presented as a percentage of the total observed incidence at each spinal segment. He noted an increased incidence of palpatory findings at the tran-

sitional areas of the spine, the occipital area, cervicothoracic spine, thoracolumbar spine, and lumbosacral spine (Fig 5).

Cox and associates⁶ reported on the incidence of somatic dysfunction in patients examined for coronary artery disease. Palpatory findings were based on range of motion, pain, soft tissue texture, and red reflex activity. A three-point scale was used by the examiners to grade the subjective impression of the degree of compliability of the paraspinal

Fig 5. Incidence of palpatory findings in ambulatory study in 200 patients by Heilig,⁵ using position, motion, and tenderness.

Fig 6. Incidence of palpatory findings in blind ambulatory cardiac study in 97 patients by Cox and associates,⁶ using range of motion, pain, tissue texture, and red reflex activity.

nal and intercostal tissue. A peak incidence was observed in the upper thoracic area and one in the upper cervical area (Fig 6).

Beal and Kleiber⁷ examined patients prior to cardiac catheterization and correlated palpatory findings with the objective evidence of coronary artery disease. Palpatory findings of somatic dysfunction were based on palpation of tissue texture changes, asymmetry of bony landmarks, and restriction in segmental spinal motion. A graph of the findings of 76 patients with diagnosed coronary artery disease shows peak incidence of spinal findings in the upper cervical area, the upper thoracic area, the lower thoracic area, and the lumbosacral area (Fig 7).

Miller⁸ plotted the incidence of palpatory findings in 44 patients with chronic obstructive pulmonary disease. Palpatory examination included tissue texture and joint motion tests. There was an increased incidence of spinal findings in the upper thoracic area (Fig 8).

Beal and Morlock⁹ reported on the incidence of spinal findings in 40 patients with diagnosed pulmonary disease. The palpatory findings were based on observations of tissue texture, symmetry of position of transverse processes and ribs, and segmental spinal mobility as determined by a compression springing test applied to the transverse process. A graph of the findings shows peak incidences in the upper cervical area, the upper thoracic and midthoracic area, and the lumbosacral area (Fig 9).

Discussion

An examination of the graphs (Figs 1-9) from the studies that have been reviewed shows that the incidence of somatic dysfunction is not uniform throughout the spine. There are peaks and valleys. The peaks occur at the transitional areas of the spine, that is, the occipital area, the cervicothoracic area, the thoracolumbar area, and the lumbosacral area. The predominant areas of incidence are the upper thoracic area and the lumbosacral area.

Variations in the reported findings may be attributed to observer influence, differences in testing procedures and their interpretation, and different subject populations. At the present time, we do not have a broadly accepted protocol of tests for the evaluation of spinal somatic dysfunction other than the general categories of tissue texture, asymmetry of bony landmarks, and segmental joint motion. Tests are individually selected by each examiner and interpreted according to his or her own criteria. Interexaminer reliability studies for assessment of tissue texture and segmental joint motion have shown poor results except in instances in which the testing procedures were prescribed and the examiners were trained in the procedures and the method of reporting results.

Hypotheses have been advanced to explain the patterns of spinal findings. However, it is evident that a single concept will not encompass the data presented or the possible etiologic factors. Chamberlin's¹⁰ concept of multiple working hypotheses

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BRIEF SUMMARY

CAUTION: Federal law prohibits dispensing without prescription.

DESCRIPTION

Seldane (terfenadine) is available as tablets for oral administration. Each tablet contains 60 mg terfenadine. Tablets also contain, as inactive ingredients: corn starch, gelatin, lactose, magnesium stearate, and sodium bicarbonate.

INDICATIONS AND USAGE

Seldane is indicated for the relief of symptoms associated with seasonal allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation.

CONTRAINDICATIONS

Seldane is contraindicated in patients with a known hypersensitivity to terfenadine or any of its ingredients.

PRECAUTIONS

Information for patients

Patients taking Seldane should receive the following information and instructions. Antihistamines are prescribed to reduce allergic symptoms. Patients should be questioned about pregnancy or lactation before starting Seldane therapy, since the drug should be used in pregnancy or lactation only if the potential benefit justifies the potential risk to fetus or baby. Patients should be instructed to take Seldane only as needed and not to exceed the prescribed dose. Patients should also be instructed to store this medication in a tightly closed container in a cool, dry place, away from heat or direct sunlight, and away from children.

Carcinogenesis, mutagenesis, impairment of fertility

Oral doses of terfenadine, corresponding to 63 times the recommended human daily dose, in mice for 18 months or in rats for 24 months, revealed no evidence of tumorigenicity. Microbial and micronucleus test assays with terfenadine have revealed no evidence of mutagenesis.

Reproduction and fertility studies in rats showed no effects on male or female fertility at oral doses of up to 21 times the human daily dose. At 63 times the human daily dose there was a small but significant reduction in implants and at 125 times the human daily dose reduced implants and increased post-implantation losses were observed, which were judged to be secondary to maternal toxicity.

Pregnancy Category C

There was no evidence of animal teratogenicity. Reproduction studies have been performed in rats at doses 63 times and 125 times the human daily dose and have revealed decreased pup weight gain and survival when terfenadine was administered throughout pregnancy and lactation. There are no adequate and well-controlled studies in pregnant women. Seldane should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic effects

Seldane is not recommended for nursing women. The drug has caused decreased pup weight gain and survival in rats given doses 63 times and 125 times the human daily dose throughout pregnancy and lactation. Effects on pups exposed to Seldane only during lactation are not known, and there are no adequate and well-controlled studies in women during lactation.

Pediatric use

Safety and effectiveness of Seldane in children below the age of 12 years have not been established.

General

Consideration should be given to potential anticholinergic (drying) effects in patients with lower airway disease, including asthma.

ADVERSE REACTIONS

Experience from clinical studies, including both controlled and uncontrolled studies involving more than 2,400 patients who received Seldane, provides information on adverse experience incidence for periods of a few days up to six months. The usual dose in these studies was 60 mg twice daily, but in a small number of patients, the dose was as low as 20 mg twice a day, or as high as 600 mg daily.

In controlled clinical studies using the recommended dose of 60 mg b.i.d., the incidence of reported

adverse effects in patients receiving Seldane was similar to that reported in patients receiving placebo. (See Table below.)

ADVERSE EVENTS REPORTED IN CLINICAL TRIALS

Adverse Event	Percent of Patients Reporting			All Clinical Studies** Seldane N = 2462	Placebo N = 1478
	Controlled Studies* Seldane N = 781	Placebo N = 665	Control N = 626***		
Central Nervous System					
Drowsiness	9.0	8.1	18.1	8.5	8.2
Headache	6.3	7.4	3.8	15.8	11.2
Fatigue	2.9	0.9	5.8	4.5	3.0
Dizziness	1.4	1.1	1.0	1.5	1.2
Nervousness	0.9	0.2	0.6	1.7	1.0
Weakness	0.9	0.6	0.2	0.6	0.5
Appetite Increase	0.6	0.0	0.0	0.5	0.0
Gastrointestinal System					
Gastrointestinal Distress (Abdominal distress, Nausea, Vomiting, Change in Bowel habits)	4.6	3.0	2.7	7.6	5.4
Eye, Ear, Nose, and Throat					
Dry Mouth/ Nose/Throat	2.3	1.8	3.5	4.8	3.1
Cough	0.9	0.2	0.5	2.5	1.7
Sore Throat	0.5	0.3	0.5	3.2	1.6
Epistaxis	0.0	0.8	0.2	0.7	0.4
Skin					
Eruption (including rash and urticaria) or itching	1.0	1.7	1.4	1.6	2.0

*Duration of treatment in "CONTROLLED STUDIES" was usually 7-14 DAYS.

**Duration of treatment in "ALL CLINICAL STUDIES" was up to 6 months.

***CONTROL DRUGS: Chlorpheniramine (291 patients), d-Chlorpheniramine (189 patients), Clemastine (146 patients)

In addition to the more frequent side effects reported in clinical trials (See Table), adverse effects have been reported at a lower incidence in clinical trials and/or spontaneously during marketing of Seldane that warrant listing as possibly associated with drug administration. These include: alopecia, (hair loss or thinning), anaphylaxis, angioedema, arrhythmia (including ventricular tachyarrhythmia), bronchospasm, confusion, depression, galactorrhea, hypotension, insomnia, menstrual disorders (including dysmenorrhea), musculoskeletal symptoms, nightmares, palpitation, paresthesia, photosensitivity, prolonged QT interval, seizures, sweating, syncope, tachycardia, tremor, urinary frequency, and visual disturbances. In clinical trials, several instances of mild, or in one case, moderate transaminase elevations were seen in patients receiving Seldane. Mild elevations were also seen in placebo treated patients. Marketing experiences include isolated reports of jaundice, cholestatic hepatitis, and hepatitis; in most cases available information is incomplete. In neither the clinical trials nor marketing experience is a causal relationship of liver abnormalities to Seldane use clear.

OVERDOSAGE

Information concerning possible overdosage and its treatment appears in Full Prescribing Information.

DOSAGE AND ADMINISTRATION

The usual dosage for adults and children 12 years and older is 60 mg (1 tablet) twice daily.

Product Information as of June, 1988

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Fig 7. Incidence of palpatory findings in blind hospital cardiac study in 76 patients by Beal and Kleiber,⁷ using tissue texture, position, and joint motion.

provides an opportunity to view all rational explanations of the observed phenomena and to propose several causes for the data rather than selecting a single determinant.

An example requiring multiple variant analysis would be a 50-year-old left-handed man who has upper thoracic and left-sided chest pain and is found to have a short left leg with a left convex scoliotic pattern and somatic findings in the upper left thoracic spine. Consideration must be given to multiple factors either acting singularly or in consort. They include a viscerosomatic reflex, left-handedness, a compensation pattern to a short left leg, and the transitional spinal area between the cervical and thoracic spine.

Several authors have emphasized the importance of the lumbosacral area and pelvis in determining musculoskeletal patterns. Dunnington¹¹ discussed a musculoskeletal stress pattern that he attributes to the body's adaptation to gravity stress. Heilig⁵ concluded that the lumbosacral area was a basic factor in altered vertebral patterns, and Magoun¹² stated that the mechanics of the sacrum makes it a key area in which other lesions show compensatory changes to sacral malalignment. The increased incidence of spinal findings at the lumbosacral area is noteworthy and may be taken as evidence to affirm the importance of the lumbosacral area.

Adaptive musculoskeletal patterns have been associated with asymmetries of the lower extremities. Schwab¹³ discussed the short-leg problem in detail. The effect of a difference in leg length on body me-

chanics has received considerable study.¹⁴ A pattern of short leg, low iliac crest, and lumbar spinal curve convex to the short-leg side occurs in about a third of the cases that are examined.

Cathie¹⁵ noted a compensatory pattern associated with the pronation syndrome which involved the tarsal bones, internal rotation of the lower extremity, increased pelvic inclination, increased lumbar lordosis, and a compensatory thoracic kyphosis.

An increased incidence of spinal segmental change in the upper thoracic spine has been attributed to head carriage and the action of the upper extremities. A convexity in the upper thoracic spine has been associated with the dominant hand.¹⁶

Heilig⁵ found an increased incidence of spinal findings at the junctional areas of the spine. A change in facet mechanics and a change in the spinal curves, which tend to occur at the junctional spinal areas, has been associated with an increased incidence of palpatory findings, as seen in Figures 1 through 9. Of special interest are the peaks of increased incidence at the cervicothoracic and lumbosacral areas.

The increased incidence of palpatory findings in the thoracic spine in the patients examined for coronary artery disease and pulmonary disease supports the concept of a viscerosomatic effect. The higher incidence of palpatory findings in the thoracic spine in the study reported by Kappler³ may also reflect a viscerosomatic component in the hospital patients examined. Of the studies reviewed, only three were not identified with subjects hav-

Fig 8. Incidence of palpatory findings in ambulatory pulmonary study in 44 patients by Miller,⁸ using tissue texture and joint motion.

Fig 9. Incidence of palpatory findings in hospital pulmonary study in 40 patients by Beal and Morlock,⁹ using tissue texture, position, and joint motion.

ing visceral disease; namely, those by Denslow,¹ Heilig,⁵ and McConnell.² Although there appears to be graphic evidence of spinal findings associated with visceral disease, there does not appear to be a clear distinction between the hospital subjects examined and the patients who were selected from an ambulatory setting.

Conclusion

The factors that have been identified as influencing the incidence of somatic dysfunction are pos-

ture, short leg, pronation syndrome, handedness, transitional areas of the spine and visceral reflexes. We need to know the natural history of somatic dysfunction, the stimuli that initiate it, how it is maintained, its stability, what influences exacerbations; and what are the effects of somatic dysfunction locally and on general body function.

The peak incidence of findings in the lumbosacral areas has been associated with complaints of low back pain. The peak incidence in the upper thoracic spine is generally attributed to the use of the

upper extremities. One can only speculate as to their potential for reflecting somatovisceral and viscerosomatic effects.

The increased incidence of findings in the transitional areas of the spine and their importance remains to be assessed as it relates to osteopathic theory and practice. A multiple factorial analysis including the variables of posture, short leg, visceral dysfunction, somatic injury or stress, and pre-conditioning influences should be the basis for the assessment of the patient's musculoskeletal history and examination.

The basic osteopathic hypothesis of the importance of somatic dysfunction on health and disease requires epidemiologic data on the incidence of somatic dysfunction in a normal or asymptomatic population. Such information is essential to develop a base line for comparative purposes with disease states and could greatly aid research in assessing the role of somatic dysfunction in health and disease.

Protocols for epidemiologic data will require a standardization of medical records of osteopathic diagnostic tests and treatment procedures. Research designs need to develop uniformity of testing methods using similar criteria for positive findings based on location, status, and significance of somatic components.

Attention to differential diagnosis evaluating palpatory findings consistent with multiple etiologic variants should give greater clarity to the importance of the factors encompassed in the diagnosis of somatic dysfunction. Coupling diagnostic information with an analysis of the response to manipulative treatment should further enhance our understanding of the role of manipulative treatment in health and disease. The need for further osteopathic clinical research in the epidemiology of the incidence of the somatic components in health and disease should be paramount.

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