

れまで慢性連日性頭痛にはさまざまな薬剤が試用されてきた。その中でもっとも広範に研究されてきたのは抗うつ薬であり、これを治療の礎石とする。三環系と SSRIs は、両者とも効果がある。

..... 文 献

※誌面の都合のためここでは総説的な論文を掲載し、参考文献は本文中にオリジナル論文の検索可能な最小限の属性を示した。

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緊張型頭痛のメカニズムと治療

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Summary


緊張型頭痛(tension-type headache)の4つの特徴は、両側性、非拍動性、軽度～中等度の痛み、体動による悪化はなしである。悪心、光・音過敏はないか、あってもわずかである。ひとことていうと「片頭痛的でない頭痛」である。緊張型頭痛は反復発作性と慢性に二大別され、前者は旧来の筋収縮性頭痛、後者は緊張性頭痛(妄想、転換反応、心気症による頭痛)に擬せられる。前者は末梢性機序(身体的ストレス、筋筋膜痛、姿勢異常、頸椎症などが原因)、後者は中枢性機序(精神的ストレス、中枢性疼痛制御系の異常)が関係する。治療については前者は生活習慣の改善、ストレッチ体操などを主体とし、後者には抗うつ薬の使用を考慮する。鎮痛薬の漫然使用は反復発作性から慢性型へ転換させる。

Lecture points

- 緊張型頭痛は頭部の重圧感を訴える頭痛であり、片頭痛と対極にある慢性機能性頭痛である。
- 緊張型頭痛は身体的・精神的ストレスに起因する頭痛である。
- 身体的ストレスは反復発作性緊張型頭痛を、精神的ストレスは慢性緊張型頭痛を起こしやすい。
- 反復発作性と慢性では治療方針が異なる。
- 片頭痛と緊張型頭痛は合併しやすい。このような例に鎮痛薬を運用すると薬剤誘発性頭痛を招来する。

Key words

反復発作性緊張型頭痛 慢性緊張型頭痛 薬剤誘発性頭痛 診断基準 治療

はじめに 

緊張型頭痛(tension-type headache)は頭部の重圧感・緊張感・不快感を示す頭痛であり、片頭痛的と対極をなす慢性機能性頭痛である。緊張型頭痛は国際頭痛学会(IHS)の頭痛分類(1988年)

で新たに採用された頭痛タイプである¹⁾。緊張型頭痛はそれまで世界的に用いられてきた米国神経学会のAd Hoc分類(1962年)のII.筋収縮性頭痛(muscle contraction headache)とV.妄想、転換反応、心気症による頭痛に相当する。

前世紀から片頭痛とは異なる頭痛には下記の二

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- 緊張型頭痛は頭部の重圧感・緊張感・不快感を示す頭痛であり、片頭痛と対極をなす慢性機能性頭痛である。
- 緊張型頭痛の共通の特徴は、器質的・代謝的疾患の背景がないことを前提にして、両側性、非拍動性、軽度～中等度の痛み、体動による悪化はなしの4点である。

表① 緊張型頭痛 (tension-type headache) の分類

2.1 反復発作性緊張型頭痛 (episodic tension-type headache)
2.1.1 頭部筋群の異常を伴う反復発作性緊張型頭痛
2.1.2 頭部筋群の異常を伴わない反復発作性緊張型頭痛
2.2 慢性緊張型頭痛 (chronic tension-type headache)
2.2.1 頭部筋群の異常を伴う慢性緊張型頭痛
2.2.2 頭部筋群の異常を伴わない慢性緊張型頭痛
2.3 上記分類に属さない緊張型頭痛
4 桁目は、頭痛の原因を示す
0. とくに原因なし
1. 下記 2～9 の複数
2. 顎関節疾患
3. 社会的心理的ストレス
4. 不安
5. 抑うつ状態
6. 妄想 (体感異常)
7. 筋肉のストレス
8. 薬剤過剰
9. 国際分類 4～12 のいずれかの合併

つの対立説が存在した。Romberg (1983) や Gowers (1888) の心因説 (psychogenic theory) と Osler (1892), Cyriax (1988), Wolff (1943) につながる筋原説 (musculogenic theory) である。Ad Hoc 分類では後者が重視され「筋収縮性頭痛」という名称が与えられた。しかし非片頭痛をすべて筋原説で説明するのは無理があり、国際分類では心因的要素も加味された「緊張型頭痛」の名称にゆり戻された。「型」が挿入されたのは、それまで流布していた緊張性頭痛 (tension headache) と区別するためである。

筋原性の頭痛と心因性の頭痛があるとすれば別個の頭痛病名をつければよさそうであるが、実態は両者のあいだにはニワトリとタマゴのような密接な相関があり、一線を画するのは不可能に近い。

そこで両者を包括した「緊張型頭痛」が採用されたのである。

坂井らの疫学調査によると片頭痛は成人の8%、緊張型頭痛は22%と約3倍の頻度で認められる²⁾。片頭痛は比較的臨床概念が明確であるのに対して緊張型頭痛の頭痛プロフィールはあいまいであり、くずかご的診断になりやすい。

1. 緊張型頭痛の分類

緊張型頭痛は国際頭痛学会 (IHS) の頭痛分類によると表①のように分類される³⁾。国際分類では、頭痛を4桁からなるコードであらわす。1桁目は頭痛の大分類で緊張型頭痛はコード2である。2桁目は1. 反復発作性緊張型頭痛 (episodic tension-type headache), 2. 慢性緊張型頭痛 (chro-

表② 緊張型頭痛の診断基準

<p>1. 2 反復発作性緊張型頭痛 (episodic tension-type headache)</p> <p>A. 以下の B~D を満たす頭痛発作が少なくとも 10 回あり、頭痛のある日数は 1 年に 180 日 (1 ヶ月に 15 日) 未満</p> <p>B. 頭痛の持続時間は 30 分~7 日</p> <p>C. 以下の痛みの少なくとも 2 つがある</p> <ol style="list-style-type: none"> 1. 圧迫感または締めつけ感 (非拍動性) 2. 強さは軽度~中等度 (生活活動は妨げられても中止するほどではない) 3. 両側性 4. 階段の昇降や類似の日常的な身体活動により増悪しない <p>D. 以下の両者</p> <ol style="list-style-type: none"> 1. 悪心、嘔吐はない (食欲不振はありうる) 2. 羞明と音過敏はないが、いずれか一方だけはありうる <p>E. 以下の少なくとも一つがある</p> <ol style="list-style-type: none"> 1. 病歴、身体・神経診察から大分類 5~11 (器質的または代謝疾患による頭痛) に含まれる疾患はない 2. 病歴、身体・神経診察から大分類 5~11 に含まれる疾患が疑われるが、適切な検査の結果、頭痛の原因ではない 3. 大分類 5~11 に含まれる疾患はあるが、頭痛のはじまりに関して緊張型頭痛と時間的に密接な関係がない <p>1. 2 慢性緊張型頭痛 (chronic tension-type headache)</p> <p>A. 以下の B~D を満たす頭痛が、6 ヶ月にわたり平均して月 15 日以上 (1 年間に 180 日) 出現する</p> <p>B. C. E. は反復発作性緊張型頭痛と同じ</p>
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nic tension-type headache), 3. 上記に属さない、のいずれかを示す。3 桁目は頭部筋群の異常の 1. ある, 2. なしを示す。4 桁目は、頭痛の原因を示す。コードの 1 例を挙げると、心労を原因とする頭部筋群の異常を伴う反復発作性緊張型頭痛は 2.1.1.4 となる。

2. 反復発作性緊張型頭痛と慢性緊張型頭痛の診断基準

反復発作性と慢性緊張型頭痛の診断基準を表②に示す。緊張型頭痛の共通の特徴は、器質的・代謝的疾患の背景がないことを前提にして、両側性、非拍動性、軽度~中等度の痛み、体動による悪化はなしの 4 点である。反復発作性緊張型頭痛は 10 回以上の頭痛歴、頭痛は年 180 日以内で月 15 回以下、持続は 30 分~7 日という条件が定められている。慢性緊張型頭痛の頻度は 6 ヶ月以上のあいだ

に 15 日/月以上 (1 年間で 180 日以上) である。基準を満たさない頭痛は 2.3 上記分類に属さない緊張型頭痛に分類される。

反復発作性緊張型頭痛は末梢性機序 (筋筋膜痛など)、慢性は中枢性機序 (疼痛制御系の異常) が主体となる。したがって鎮痛薬は前者には有効であるが、後者には無効であり抗うつ薬が有効となる。

3. 緊張型頭痛のプロフィール

緊張型頭痛は男女差はあまりなく、やや女性に多い程度である。後頭部から項部を中心とする圧迫感、緊迫感、被帽感、頭重感が主体である。頭痛の程度は仕事・家事の遂行を妨げない。両側性のことが多いが約 1/3 は一側性である。頭痛の持続時間は 30 分~7 日とさまざまである。頭痛の性状はいつとはなしにはじまる非拍動性頭痛である

- 緊張型頭痛はしばしば片頭痛と合併する。
- 緊張型頭痛は身体的・精神的ストレスから誘発される。
- 緊張型頭痛は筋の持続的収縮だけでなく、精神的緊張によっても痛みを感知する中枢側の異常が発生して頭痛が生じる。

が、ズキズキすると訴えられることもある。片頭痛と違って軽い悪心、光・音過敏はあっても嘔吐を伴うことはない。しばしば肩凝りやめまい感を随伴する。

軽快因子は入浴・飲酒・運動（血管性頭痛では増悪因子となる）であり、増悪因子は、ストレス、疲労、睡眠不足、不規則食事、読書、運転などである。背景要因としてはリラックスできない性格、マイナス思考、神経質、完全主義などの性格的素因に加えて、社会的心理的ストレス、不安、抑うつ、心気性などの因子が頭痛の発症に関与している⁴⁾⁶⁾。

緊張型頭痛はしばしば片頭痛と合併する(62%)。臨床現場では緊張型頭痛と片頭痛の見きわめが困難な例も少なくなく、混合型頭痛という病名があると便利であるが、国際分類ではそのような頭痛タイプは設けず、同一患者に併存したものととらえる。緊張型頭痛では頭半棘筋が大後頭神経を拘縮して神経痛を合併することがある。

4. 緊張型頭痛のリスクファクター

緊張型頭痛は身体的・精神的ストレスから誘発される。鶴首、なで肩（鎖骨低位）、頸椎のアライメント不良、姿勢不良（うつむき姿勢、高すぎる枕）は頸筋に負担をかけ身体的ストレスの原因となる。たとえば頭を水平より20～30度下向きにさせると、約1分で張った感じが現れ、2～3分で頭痛が起こる⁶⁾。精神的ストレスも血管を収縮させ筋阻血を起こす。暗算をさせると、筋電図の変化なしに血流量は安静時の50～70%に減少する。疲労は痛みの閾値を低下させ、頭痛を感じやすくする。これらの変化は個人差が大きく、ストレスや精神的な緊張に弱い体質・性格がある⁶⁾。ほかに

眼精疲労や近見作業、顎関節の異常、歯ぎしり・食いしばるくせも頭痛を誘発する。最近はタイピストや縫製作業に代わりパソコン作業が緊張型頭痛の有力な原因となっている。

5. 反復発作性緊張型頭痛の発生機序

身体的・精神的ストレスにより、頭蓋筋の持続的収縮が起こる。それが長引くと阻血性筋収縮が起こり、乳酸、ピルビン酸など発痛物質が発生し、疼痛が起こる。疼痛は交感神経の活動を高め、痛覚線維を過敏にし筋肉の持続的収縮をもたらす。頭が痛いこと自体もストレスとなる。かくして一連の悪循環が完成すると頭痛は遷延する。能動的な運動の場合は反射的に筋血流が改善するので疼痛を生じにくい⁶⁾が、受動的な運動の場合は筋血流の低下がつづきやすい⁶⁾。

緊張型頭痛に筋収縮が関与することは、古くはWolff (1963) が筋電図で筋収縮を証明し、局所麻酔薬で頭痛が消失することにより証明した。作田⁶⁾はうつむきにより筋放電と筋肉血流の減少（安静時の1/3程度）が起こることを実証した。Sakai ら⁷⁾は筋硬度測定法により僧帽筋や後頸筋群の硬度が高いことを観察した。

緊張型頭痛は筋の持続的収縮だけでなく、精神的緊張によっても痛みを感知する中枢側の異常が発生して頭痛が生ずる⁶⁾。不安・抑うつ・ストレスがあると大脳辺縁系に作用して、疼痛知覚閾値低下、疼痛抑制系の障害、中枢での神経伝達物質の異常、エンドルフィンの低下などの中枢性因子により、中枢性・末梢性に疼痛過敏となり、緊張型頭痛が誘発される⁶⁾。

緊張型頭痛は合目的的に考えると身体的・精神的ストレスに対して生体を防御する反応（デファ

● 鎮痛薬を3ヵ月連日のように服用すると片頭痛は変容型片頭痛となり、反復発作性緊張型頭痛の場合も慢性緊張型頭痛に変容する。このような薬過剰服用による慢性連日性頭痛を薬剤誘発性頭痛という。

● 薬剤誘発性頭痛を防ぐには、鎮痛薬の服用を月10回までにとどめることである。

ンス)である。過激な運動により息切れ・動悸や筋肉痛が、過食により胃部膨満と胃痛が現れるのとの同様の反応である。精神的緊張により頭蓋筋の収縮が起こるデファンスのもっとも典型的な例が「カメのくびすくめ」である。

6. 薬過剰服用による慢性連日性頭痛

慢性頭痛に悩む患者は苦痛を免れたいために、常時鎮痛薬を連用する傾向がある。鎮痛薬を3ヵ月連日のように服用すると片頭痛は変容型片頭痛となる。反復発作性緊張型頭痛の場合も慢性緊張型頭痛に変容する。薬過剰服用による慢性連日性頭痛を薬剤誘発性頭痛 (drug-induced headache) という¹⁰⁾。薬剤誘発性頭痛の発生機序は central sensitization (痛覚制御系の変調) によるとされる。

薬剤誘発性頭痛を防ぐには鎮痛薬の服用を月10回までにとどめる。混合型頭痛でそれ以上服用を要する場合は片頭痛予防薬を使う。緊張型頭痛は本来鎮痛薬は必要としない程度の頭痛であるが、不安やうつがあると疼痛を強く感じ、強迫的に鎮痛薬を服用しがちになる。この場合は鎮痛薬の連用を中止させるとともに、疼痛知覚閾値を上昇させる治療、具体的には抗うつ薬の服用を勧める。

7. 緊張型頭痛の診察

頭痛の診断は問診と神経学的所見につき³⁾⁹⁾といわれる。緊張型頭痛に固有な診察としては、触診により頸部・肩の筋の庄痛と硬結をチェックする。後頭神経の庄痛も診ておく。筋肉の過緊張の検査、とくに安楽椅子徴候 (armchair sign, Lance 1973) が重要である¹¹⁾。この検査はアーム

チェアでくつろぐ姿勢をとらせ、力をまったく除くように命ずる。その後、検者は腕の支えを取り除く。緊張型頭痛患者はリラックスする能力に欠けるため、腕がパタンと落ちず、見えないアームチェアに腕を乗せたままである。見えない枕 (invisible pillow, Lance 1973) とは患者を仰臥位として頭を持ち上げ、力を抜くように命じておいて手の支えを外す。患者の頭は「見えない枕」があるかのように、空中にとどまる。下顎開閉試験 (up-and-down of jaw, Lance 1973) とは開口位で患者をリラックスさせて検者が顎を小幅に上下動させる。緊張型頭痛は顎ではなく頭が動いてしまう。

緊張型頭痛はうつ状態・うつ病、身体表現性障害、心因性疼痛障害、分裂病 (頭痛幻覚、頭痛妄想) などと鑑別が必要となる¹²⁾。このなかでもうつ状態・うつ病患者は緊張型頭痛を主症状として一般外来を訪れるのでとくに注意を要する。うつに随伴しやすい睡眠障害の有無ははかならず問診する。疑わしい場合は心療内科・精神科に併診をすすめる。

8. 緊張型頭痛の検査

頭蓋内器質的疾患が疑われればCT/MR検査をおこなう。緊張型頭痛はしばしば生理的前弯の消失 (straight neck や後弯) などの頸椎の異常が潜在している。頸椎レントゲン撮影は積極的におこないたい。頸椎の前弯消失の要因の一つは forward head posture (猫背) である。頭が前に出た結果としてC2がC7より前に出て、形態的に変化が生じる。前傾した重い頭を支えるため後頸部の筋肉 (とくに僧帽筋、半棘筋) が緊張し、筋筋膜疼痛を生じ、頭部に関連痛を放散して頭痛と

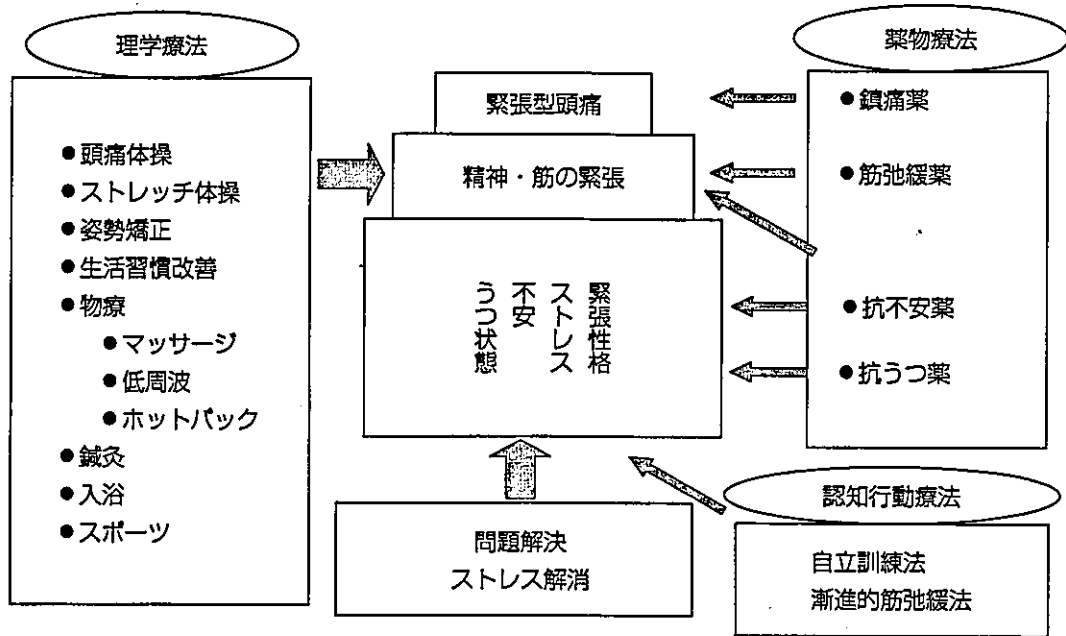


図1 緊張型頭痛の階層的治療
緊張型頭痛の場合は複眼的治療が要求される。つねに頭痛の原因となる基層から治療を構成する。

なる。頭重負荷指数(頭痛指数)の測定⁶⁾も診断の補助となる。そのほか特殊な検査法として筋電図検査¹³⁾、ES 2 (exteroceptive suppress period, 脳幹の抑制系ニューロンの機能低下を見る)⁹⁾、筋硬度計検査⁷⁾、サーモグラフィー検査などが挙げられる。

9. 緊張型頭痛の治療

緊張型頭痛の治療は非薬物的治療、薬物治療、補助療法に分けられる。図1に示すように緊張型頭痛の発生過程を階層的に考察して治療方針を組み立てることが大切である¹⁴⁾。反復発作性緊張型頭痛は性格生活習慣に起因する慢性頭痛であるので薬物療法を主体とすべきではない。具合のよいときは減量し、過剰投与とならないよう注意する⁹⁾。安易な鎮痛薬や抗不安薬の連用はかえって頭痛をこじらせる¹⁰⁾。

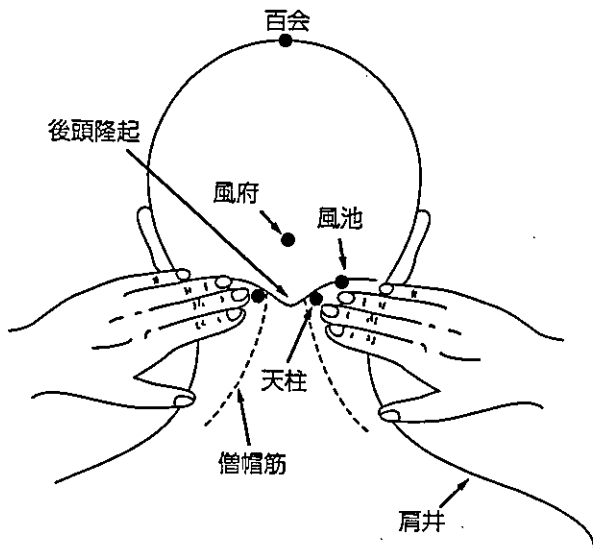
ストレスを解決する。不安や緊張あるいは抑うつの原因を、意識下のものも含めて探り出す。そのうえで原因の解消あるいはストレスに対する対処方法を指導する。たとえば交通事故のトラブルに起因する場合は早期解決をはかる。日常生活でも適宜な気分転換をおこない、心身とも過緊張の状態がつかないように指導する。とくにうつむき姿勢の是正は頭痛対策のポイントとなる⁶⁾。不規則な食事、悪い睡眠習慣、運動不足を解消する。仕事も根をつめないでリラックスできる時間と軽いストレッチを挿間するよう指導する。心理療法も重要で緊張型頭痛の成り立ちの説明と「脳はなんともないですよ」という保障も頭痛の軽快因子となる。ちなみに患者が実際におこなっている緊張型頭痛の軽減法はマッサージ、運動、睡眠、安静、湿布、指圧・圧迫、入浴などである(北里大学調べ)。

1) 非薬物的治療

まず緊張型頭痛の大元である精神的・身体的ス

2) 薬物療法

痛みに対しては鎮痛剤を頓用で処方するが、連



図② 天柱マッサージ

天柱は外後頭隆起から2横指ほど外側で僧帽筋の外縁と後頭骨下端の陥凹部。両方の四本の指(II~IV)を全体にやや屈曲させ、中指を天柱ツボにあてて左右に往復させる(数分)。緊張型頭痛、頸凝り、肩凝り、疲れ目によく効く。(原案：上村孝臣)

用・過剰を避ける。頭頸部のこりが強ければ筋弛緩剤(例：チザニジン3錠分3)を、不安・不眠に抗不安薬を投与する[例：不眠・不安がある場合デパス(0.5)1錠眠前，不安・焦燥が強ければ短期間にかぎりエチゾラム(0.5)3錠(分3)]。抑うつ状態があれば抗うつ薬を併用する。慢性緊張型頭痛の場合は鎮痛剤やエルゴタミン製剤の連用(鎮痛薬などを連日3ヵ月以上使用している)をチェックする。薬剤誘発性頭痛と認められれば原因薬を中止する。慢性緊張型頭痛に対しては確立された治療法はないが、そのなかでも抗うつ薬の評価が高い¹⁵⁾。アミトリプチン10~30mg(眠前分1)，SSRI[パソキセチン10~30mg(夕食後分1)，マレイン酸フルボキサミン50mg(分2)]を投与する。著者は40歳前の患者にはアミトリプチン，それ以降の患者にはSSRIを選択している。後頭神経痛の要素が加わっている場合は，カルバマゼピン(200mg)1~2錠(分2)を投与する。

3) 補助療法

筋の圧痛や硬結がある場合は筋肉の圧痛点に局麻剤を注射するトリガブロックは効果が大きい¹⁶⁾。物理療法(ホットパック，低周波，レーザー照射)，パップ剤はしばしば緊張型頭痛の治療に利用されている。簡単には天柱マッサージ(図②)や温熱治療(電子レンジで暖めたタオルを頸部にあてる)は頸肩腕にこりのある場合に有用である。鍼灸・漢方も治療選択肢のひとつである。最近ではハーブ療法やアロマテラピーにも関心がもたれている。認知行動療法としてはバイオフィードバック法(筋電図を音に変換し緊張を患者に認知させリラックス法を体得させる)，漸進的弛緩法(リラクゼーション法のひとつ)，自律訓練法があるが，わが国では指導者が少なく普及度は低い。

おわりに

片頭痛はトリプタンの登場により，治療の路が拓けたが，緊張型頭痛は決め手になる治療法がなくかえって治療に難渋する。緊張型頭痛をうまく治療するには全人的かつ包括的なアプローチが大切である。また反復発作性緊張型頭痛と慢性緊張型頭痛のふたつの異質な頭痛が存在することを念頭において診断と治療を進めるべきである。

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雜 誌

平成 15 年度

Reliability and Validity of the Japanese Migraine Disability Assessment (MIDAS) Questionnaire

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Objective.—This study was designed to assess the test-retest reliability, internal consistency, and validity of a Japanese translation of the Migraine Disability Assessment (MIDAS) Questionnaire in a sample of Japanese patients with headache.

Background.—Previous studies have demonstrated that the English-language version of the MIDAS Questionnaire is a reliable and valid instrument for the assessment of migraine-related disability. Any translations of the MIDAS Questionnaire must also be assessed for reliability and validity.

Methods.—Study participants were recruited from the patient population attending either the Neurology Department of Kitasato University or an affiliated clinic. Participants were eligible for study entry if they had 6 or more primary headaches per year. For reliability testing, participants completed the MIDAS Questionnaire on 2 occasions, exactly 2 weeks apart. To assess validity, patients were also invited to participate in a 90-day daily diary study. Composite measures from the 90-day diaries were compared to equivalent MIDAS measures (ie, 5 questions on headache-related disability and 1 question each on average pain intensity and headache frequency in the last 3 months) and to the total MIDAS score obtained from a third MIDAS Questionnaire completed at the end of this 90-day period.

Results.—One hundred one patients between the ages of 21 and 77 years were recruited (81 women and 20 men). Ninety-nine patients (80 women and 19 men) participated in the diary study. At baseline, 46.5% of patients were MIDAS grade I or II (minimal, mild, or infrequent disability), 22.2% were MIDAS grade III (moderate disability), and 31.3% were MIDAS grade IV (severe disability). Test-retest Spearman correlations for the 5 disability questions and the questions on average pain intensity and headache frequency ranged from 0.59 to 0.80 ($P<.0001$). The test-retest Spearman correlation coefficient for the total MIDAS score was 0.83 ($P<.0001$). The degree to which individual MIDAS questions correlated with the diary-based measures ranged from 0.36 to 0.88. The correlation between the total MIDAS score and the equivalent diary-based measure was 0.66. In general, the mean and median values for the MIDAS items and total MIDAS score were similar to the means and medians for the diary-based measures. However, the mean MIDAS scores for the number of days on which headache was experienced and the number of missed workdays were significantly different compared to the diary-based estimates for these items ($P<.05$). In addition, the mean MIDAS score for the number of days of missed housework was significantly higher than the corresponding diary-based estimate ($P<.01$).

Conclusions.—The results from this study show that the Japanese translation of the MIDAS Questionnaire is comparable with the English-language version in terms of reliability and validity.

Key words: disability, headache, Japan, migraine, MIDAS, reliability, validity

Abbreviations: MIDAS Migraine Disability Assessment

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The Migraine Disability Assessment (MIDAS) Questionnaire is a short, self-administered questionnaire designed to quantify headache-related disability over a 3-month period. The MIDAS score is based on 5 disability questions in 3 domains of activity: questions 1, 3, and 5 assess the number of missed days due to headache in school or paid work, housework, and family, social, or leisure activities; questions 2 and 4 assess the number of additional days with significant limitations to activity (defined as at least 50% reduced productivity) in the paid work and housework domains. The MIDAS score is the sum of responses to questions 1 through 5. Two supplemental questions (A and B) provide the physician with additional clinical information about headache frequency and the average pain intensity of headaches over the previous 3 months.

Previous studies have demonstrated that the English-language version of the MIDAS Questionnaire (Figure 1) is reliable (ie, there is high consistency between results when the MIDAS Questionnaire is administered twice to the same individual 2 to 3 weeks apart)^{1,2} and valid (ie, information captured by MIDAS, a retrospective questionnaire, correlates highly with data captured prospectively by a daily diary).^{3,4} The MIDAS score also correlates strongly with clinical judgment of the severity of a patient's condition and predicts clinical judgment regarding the need for medical care as well as treatment outcomes.^{5,6} Accordingly, MIDAS has been recommended as a tool for public health initiatives designed to reduce the burden of migraine.⁷

Recent studies suggest that public health initiatives are needed in Japan to improve the diagnosis and treatment of migraine. A nationwide survey revealed that the overall prevalence of migraine in Japan was 8.4% (5.8% without aura and 2.6% with aura).⁸ Consultation rates were low, with 69.4% of patients with migraine never having consulted a physician for headache. Despite this, 74.2% complained that migraine significantly impaired their daily activity. Only 11.6% were aware that their headaches were migraine, and the majority (56.9%) used over-the-counter medications to manage their illness, to the exclusion of prescription drugs.

To address public health needs, a Japanese-

language version of the MIDAS Questionnaire (Figure 2) was developed through a process of translation and back translation. To determine whether the translation was conceptually and semantically equivalent to the English version of the MIDAS Questionnaire, we evaluated the reliability, internal consistency, and validity of the Japanese MIDAS Questionnaire among patients seeking care for headache in Japan. To assess test-retest reliability, we administered the questionnaire to the same individuals twice. To assess validity, we conducted a 90-day diary study similar to the original study that was undertaken to evaluate the validity of the English-language version of MIDAS.⁴

METHODS

Recruitment of Study Population.—Patients seeking care at the Neurology Department of Kitasato University (Kanagawa, Japan) or an affiliated clinic and reporting 6 or more primary headaches per year were eligible for the study. All study participants were evaluated by a study clinician and assigned a headache diagnosis. A migraine diagnosis was based on the International Headache Society (IHS) criteria for migraine.⁹

Recruitment took place between July and November 2000 (first patients were recruited for reliability testing on July 12 and the last on November 18, 2000). Written informed consent was obtained before any data were collected. The trial was designed and monitored in accordance with the ethical principles of Good Clinical Practice as required by the regulatory authorities, and in accordance with the Declaration of Helsinki.


A previous pilot study conducted at the Neurology Department of Kitasato University indicated that patients seeking care at this clinic generally have a broad range of MIDAS scores. Patients were grouped into 3 categories at baseline: MIDAS grades I and II (score 0 to 10; minimal, mild, or infrequent disability), MIDAS grade III (score 11 to 20; moderate disability), and MIDAS grade IV (score 21 or above; severe disability).

Reliability Testing.—Patients recruited into the reliability study completed a MIDAS Questionnaire on 2 occasions, 2 weeks apart. The 2-week interval was selected as a period short enough to eliminate

This form can help you and your doctor improve the management of your headaches

Do You Suffer From

headaches?



MIDAS QUESTIONNAIRE

INSTRUCTIONS: Please answer the following questions about ALL your headaches you have had over the last 3 months. Write your answer in the box next to each question. Write zero if you did not do the activity in the last 3 months.

- 1 On how many days in the last 3 months did you miss work or school because of your headaches? days
- 2 How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (Do not include days you counted in question 1 where you missed work or school) days
- 3 On how many days in the last 3 months did you not do household work because of your headaches? days
- 4 How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (Do not include days you counted in question 3 where you did not do household work) days
- 5 On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches? days


TOTAL days

- A On how many days in the last 3 months did you have a headache? (If a headache lasted more than 1 day, count each day) days
- B On a scale of 0-10, on average how painful were these headaches? (Where 0 = no pain at all, and 10 = pain as bad as it can be)

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Once you have filled in the questionnaire, add up the total number of days from questions 1-5. Do not include the answers to Questions A and B in the overall score.

Grading system for the MIDAS Questionnaire:		
Grade	Definition	Score
I	Minimal or infrequent disability	0-5
II	Mild or infrequent disability	6-10
III	Moderate disability	11-20
IV	Severe disability	21+



The MIDAS programme is sponsored by




Fig. 1.—English version of the Migraine Disability Assessment (MIDAS) Questionnaire.

the likelihood of significant changes in the patient's illness severity, but long enough to ensure that patients did not recall their responses to the first questionnaire. The first MIDAS Questionnaire was completed during a consultation, and the patient was given

guidance on its completion. The second MIDAS Questionnaire was either mailed back to the study center in a reply-paid envelope or brought back by the patient during the next scheduled visit (agreed on an individual basis by the investigator and partici-

MIDAS質問表

記入のしかた: 過去3ヶ月の間にあったすべての頭痛について、以下の質問に答えてください。それぞれの質問の右側の欄に答えを記入して下さい。過去3ヶ月の間に該当する出来事がなければ0(ゼロ)と記入して下さい。

1. 過去3ヶ月の間で、頭痛のために仕事または学校を休んだ日が何日ありましたか。 ___日

2. 過去3ヶ月の間で、頭痛のために仕事や学校での勉強が、いつもの半分以下しかできなかった日が何日ありましたか。(問1で、仕事または学校を休んだ日がある場合は、その日数は入れないでください。) ___日

3. 過去3ヶ月の間で、頭痛のために家事ができなかった日が何日ありましたか。 ___日

4. 過去3ヶ月の間で、頭痛のために家事がいつもの半分以下しかできなかった日が何日ありましたか。(質問3で家事ができなかった日がある場合はその日数は入れないでください。) ___日

5. 過去3ヶ月の間で、頭痛のために家族での行事や、付き合い・用事や遊びができなくなった日が何日ありましたか。 ___日

合計 ___日

.....

A. 過去3ヶ月の間で、頭痛のあった日は何日ありましたか。(頭痛が1日以上続いた場合は、それぞれの日を1日と数えてください。) ___日

B. 頭痛の程度について、0-10点で採点するとすれば、平均何点でしたか。(この場合、まったく頭痛がなかった場合は0点、これ異常ないくらい痛かった場合を10点とします。) ___日

MIDAS質問表 Grade 分類

Grade	Score	Definition
I	0-10	軽度の支障あり
II	11-20	中等度の支障あり
III	21以上	重度の支障あり

Fig. 2.—Japanese translation of the Migraine Disability Assessment (MIDAS) Questionnaire.

pant). Responses to the MIDAS questions recorded days missed from work, school, and leisure activities during the preceding 3 months. As such, the recall intervals for the 2 MIDAS Questionnaires and over which patients recalled the days missed from work, school, and leisure activities due to headache had, approximately, an 83% overlap in time (10 of the 12 weeks). During this time, no change in acute or prophylactic medication was permitted.

Validity Testing.—To test the validity of the Japanese MIDAS Questionnaire, all patients participating in the reliability study were asked to complete a

daily headache diary for 90 days. Participants were instructed to complete the daily diaries at the same time each day (preferably immediately prior to bedtime) for 90 days. The daily diary comprised 2 parts and assessed information regarding the activities undertaken by an individual on any given day.

In part I, patients recorded information about work outside the home (ie, paid or schoolwork), housework, mood and stress, menstrual status, and presence of head pain. Patients completed the second part of the diary only on days on which they had a headache. Specific information recorded in part II of

the diary cards included: headache features, including pain intensity, headache duration, pain features, and associated headache symptoms (used to define the type of headache); inability to attend work or school for all or part of the day, and an indication of the extent to which productivity was reduced when individuals continued to work during an attack; inability to perform housework for all or part of the day, and an indication of the extent to which productivity was reduced when individuals continued to undertake housework during an attack; inability to participate in family and leisure activities; and medications used to treat the headache.

Study participants were asked to return the diaries in a reply-paid envelope at the end of each week for the 13 weeks of the validity study. Follow-up telephone calls were made to those participants who failed to return their diaries on schedule. At the end of the 13-week diary period, participants were either asked to make a further visit to the study center to complete another MIDAS Questionnaire or sent a MIDAS Questionnaire to be completed and returned in a stamped, self-addressed envelope (agreed on an individual basis by investigator and participant).

Statistical Analysis of MIDAS Test-Retest Reliability.—Spearman and Pearson correlation coefficients were calculated between the individual questions and the overall MIDAS score to assess the degree to which responses to the first and second questionnaires were related. As expected, response data to individual MIDAS questions and the overall MIDAS score were skewed towards higher values. Spearman rank correlation was, therefore, preferred in the assessment of test-retest reliability. Means were compared between test and retest for all MIDAS components using *t* tests and Wilcoxon signed rank tests.

The internal consistency (ie, the extent to which each item on assessment is answered in the same way as the other items) of the MIDAS score was assessed using Cronbach α , a measure that is analogous to a split-half reliability assessment. An α of .7 is considered acceptable; an α of .8 or greater indicates excellent internal consistency.

Statistical Analysis of MIDAS Validity (Daily Diary Measures Versus MIDAS Scores).—The validity of MIDAS questions 1 through 5, MIDAS questions

A and B, and the total MIDAS score obtained using the Japanese MIDAS Questionnaire were assessed by comparing these results with equivalent composite measures summarized from the diary measures. More than one reference measure from daily diary measures was derived for each MIDAS question (Table 1).

Patient diary card information on number of days with headache and pain intensity were summarized for all headaches. Two methods were used to derive a diary-based measure equivalent to the total MIDAS score. The methods differed in the way the total reduced productivity time at work and in housework was estimated, although both expressed total reduced productivity time in each domain as lost days. The count of reduced productivity days for method 1 was based on the number of days with headache where productivity was reduced by half or more. For method 2, the count was based on the sum of reduced productivity across all days. The count of missed days at work or in housework was the same for methods 1 and 2 and based on diary days for all or part of the study.

Mean and median values for diary items and MIDAS questions were compared using paired *t* tests and the signed rank test. Correlation coefficients were used to compare: (1) the individual MIDAS questions with the equivalent diary measures, and (2) the diary-based disability measurement and total MIDAS score. Responses from MIDAS Questionnaires, which were completed at the beginning and end of the 90-day diary period, were included in the analysis.

RESULTS

Population Demographics.—One hundred one patients between 21 and 77 years of age were enrolled in the reliability study. However, 2 participants did not provide complete answers and were omitted from the analysis resulting in a sample of 99 participants for the reliability portion of the study (80 women [29 not in paid work] and 19 men). Ninety-four of these (75 women and 19 men) participated in the validity study. The mean age for the total population from the reliability sample was 42.7 years (standard deviation, 13.4). The distribution of MIDAS scores at baseline was as follows: MIDAS grades I and II, 46.5%; MIDAS grade III, 22.2%; and MIDAS grade IV, 31.3%. Fifty (51%) of the 99 patients who

Table 1.—Migraine Disability Assessment (MIDAS) Questions and Equivalent Measures Derived From the Daily Headache Diary

MIDAS Item	Equivalent Diary Measure
(1) On how many days in the last 3 months did you miss work or school because of your headaches?	<ul style="list-style-type: none"> • Number of full missed workdays • Days on which work was missed for all or part of the day
(2) How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches?	<ul style="list-style-type: none"> • Days on which productivity was reduced by half or more • Sum of reduced productivity on headache days
(3) On how many days in the last 3 months did you not do household work because of your headaches?	<ul style="list-style-type: none"> • Number of full missed days of household chores • Number of days on which household work was missed for all or part of the day
(4) How many days in the last 3 months was your productivity in household work reduced by half or more because of your headache?	<ul style="list-style-type: none"> • Days productivity was reduced by half or more • Sum of reduced productivity on headache days
(5) On how many days in the last 3 months did you miss family, social, or leisure activities?	<ul style="list-style-type: none"> • Number of missed leisure days
(A) On how many days in the last 3 months did you have a headache?	<ul style="list-style-type: none"> • Total days with headache • Total number of headaches • Total days with migraine headache
(B) On a scale of 1-10, on average, how painful were these headaches? (0 = no pain at all and 10 = pain as bad as it can be)	<ul style="list-style-type: none"> • Average pain intensity for all headaches • Average pain intensity for migraine headaches

took part in the 90-day diary study met IHS diagnostic criteria for migraine.⁹ Headache diagnoses for the 99 patients who participated in the reliability study are summarized in Table 2.

Reliability.—Test-retest reliability of individual MIDAS questions was good to excellent, with correlation coefficients ranging from 0.59 (missed days of leisure activity) to 0.80 (reduced productivity at work or school) ($P < .0001$; Table 3).

Migraine Disability Assessment question A (pain intensity) and question B (headache frequency) also showed good to excellent test-retest reliability with correlation coefficients of 0.87 (pain intensity) and 0.66 (headache frequency) ($P < .0001$). The correlation for the overall reliability of the total MIDAS score was 0.83 ($P < .0001$). Comparing mean values between the test-retest MIDAS Questionnaires, a statistically significant difference was observed for MIDAS question 1 ($P = .002$; MIDAS test mean, 2.2 [± 7.0] versus MIDAS retest mean, 2.9 [± 8.2]). All other means were comparable by either the signed rank test or by paired t test (Table 3).

Cronbach α for the 5 MIDAS questions was .69.

However, examination of the distributions and the total MIDAS scores revealed 4 participants who were either outliers or were highly influential in the validity analysis (or both). After the 4 participants were removed, Cronbach α increased to .82.

Correlations Between MIDAS Responses and Diary Data.—Correlation coefficients between individual MIDAS questions and the diary-based measures ranged from 0.36 (missed days of housework) to a high of 0.88 (days on which headache was experienced; Table 4).

The correlation coefficient for a composite measure of headache impact on housework (ie, missed days of housework plus days on which housework was reduced by half or more) between MIDAS and the equivalent diary-based measure was 0.65.

The correlation coefficient between the total MIDAS score and the recorded diary based equivalent measures was 0.66.

Comparison of MIDAS Responses and Diary-Based Estimates.—The mean number of missed workdays from MIDAS (0.89) was less than the diary measure for missing work/school for all or part of the

Table 2.—Headache Diagnoses for Patients who Participated in the Reliability Study

	No. of Patients With Migraine Only	No. of Patients With Tension-type Headache Only	No. of Patients With Migraine and Tension-type Headache	Total
Sex				
Male	5	12	2	19
Female	45	16	19	80
Age, y				
20-29	10	7	4	21
30-39	11	5	6	22
40-49	10	3	4	17
50-59	16	12	4	32
>60	3	1	3	7
Total, No. (%)	50 (50.5)	28 (28.3)	21 (21.2)	99 (100)

day (2.31) ($P < .01$) and greater than the diary measure for full missed work/school days (0.57) ($P < .05$).

The MIDAS and diary-based measures for the number of days where productivity was reduced by

half or more in work/school were not significantly different from each other (MIDAS mean of 2.64 [± 5.47] versus diary mean of 2.52 [± 4.40] for work/school). A similar pattern was observed for days on which the

Table 3.—Summary of Migraine Disability Assessment (MIDAS) Data From Test-Retest Reliability Study of the Japanese Translation of the MIDAS Questionnaire

MIDAS Question	Baseline (n = 99)		Retest (n = 99)		Spearman Correlation
	Mean (SD)	Median	Mean (SD)	Median	
(1) On how many days in the last 3 months did you miss work or school because of your headaches?	2.2 (7.0)	0.0	2.9 (8.2)*	0.0	0.74†
(2) How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (n = 98)	5.1 (9.0)	1.0	5.3 (7.8)	1.0	0.80†
(3) On how many days in the last 3 months did you not do household work because of your headaches?	3.6 (4.8)	2.0	3.9 (5.0)	2.0	0.76†
(4) How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches?	5.6 (6.4)	3.0	5.7 (6.2)	3.0	0.73†
(5) On how many days in the last 3 months did you miss family, social, or leisure activities because of your headaches?	3.5 (5.0)	2.0	4.2 (6.2)	2.0	0.59†
Total MIDAS score	19.7 (20.1)	12.5	21.7 (22.1)	14.0	0.83†
(A) On how many days in the last 3 months did you have any headache?	30.9 (28.2)	20.0	31.7 (28.9)	18.0	0.87†
(B) On a scale of 0-10, on average how painful were these headaches?	5.7 (1.8)	6.0	5.6 (1.9)	5.0	0.66†

* $P = .002$ for signed rank test comparing test and retest values. All other comparisons of distributions were not significantly different.
† $P < .0001$.

ability to do housework was reduced by half or more (MIDAS mean of 5.39 [± 8.88] versus diary mean of 5.74 [± 8.29]).

The mean number of missed days of housework from MIDAS (2.78) was less than the diary measure for missing housework for all or part of the day (6.73) ($P < .01$) and greater than the diary measure for full missed days of housework (0.78) ($P < .01$). However, for the composite measure of headache impact on housework, the means were 8.17 [± 12.58] versus 6.52 [± 9.50].

The number of days with headache in the past 3 months (assessed by MIDAS question A) was low compared with the diary-based measure (mean, 31.6 [± 28.72] versus 40.8 [± 33.28]; $P < .01$). The level of pain intensity, recorded by MIDAS question B, was similar to the prospective diary-based measure (mean, 4.9 [± 1.94] versus 4.6 [± 1.48]).

Two methods were used to derive a diary-based measure equivalent to the total MIDAS score. While method 2 is considered to be the more relevant measure, the number of days for methods 1 and 2 for this patient population were similar and produced "scores" that were significantly greater than the mean total MIDAS score (MIDAS, 13.98 [± 19.67]; diary method 1, 20.57 [± 24.91], $P < .01$; diary method 2, 21.42 [± 24.34], $P < .01$).

COMMENTS

Our findings indicate that the reliability and validity of the Japanese translation of the MIDAS Questionnaire is comparable with the English-language version evaluated in population-based samples of migraine and other headache sufferers in the United States and United Kingdom.^{1,2,4}

The reliability of the Japanese translation of the MIDAS Questionnaire was evidenced by moderate consistency across all questions (Cronbach α , .69). Deletion of several outliers and very influential data points ($n = 4$) produced a higher Cronbach α of .82.

Good to excellent test-retest correlations were found for individual MIDAS questions and the total MIDAS score. The test-retest correlation for the total MIDAS score (0.83) was similar to that observed in the US (0.78) and UK (0.77) studies.^{1,2,4}

The Japanese MIDAS Questionnaire also provides a valid estimate of disability time when compared with a diary assessment of disability. Correlation coefficients between MIDAS and comparable diary-based measures obtained in this study were also very similar to those obtained during the validity testing of the English MIDAS Questionnaire.^{3,4} The correlation between the MIDAS score and equivalent composite diary measures was good (0.66). We consider this to be a relatively strong correlation given that the measures being compared were based on very different methods of collecting data (ie, retrospective versus prospective recording of information) and given that the test-retest correlation for the MIDAS score itself is 0.83.¹

When comparing the MIDAS and diary-based measures, the mean scores and the correlation provide complementary information. The results suggest that when the mean scores are comparable (eg, for the paid work, housework, and leisure domains), migraineurs provide accurate information. In contrast, when the mean scores differ, as in the case of number of headaches, sufferers of migraine headache either underestimate the severity of individual attacks or selectively recall their more severe headaches. Overall, the MIDAS scores were not biased, and this finding supports the accuracy of population-based survey estimates of the burden of disease when frequency-based questions are used. The high correlation for the MIDAS score, when combined with information on accuracy of group estimates, suggests that individuals report headache-related disability in a consistent manner.

All previous work in the United States and United Kingdom on establishing the reliability and validity of the MIDAS Questionnaire has been carried out amongst population-based samples. This study extends the findings to a clinic-based population.

Establishing the reliability and validity of the Japanese translation of the MIDAS Questionnaire is important to confirm linguistic compatibility and to ensure cross-cultural clinical relevance. The results from this study confirm that the Japanese translation is suitable as a means of assessing headache-associated disability and, hence, may improve communication between Japanese headache sufferers and their physicians.

Table 4.—Summary Statistics and Correlation Coefficients for Migraine Disability Assessment (MIDAS) Scores Obtained at the End of the Diary Period and for Equivalent Measures Derived From the Diary

MIDAS Item	MIDAS Mean (SD)	MIDAS Median	Equivalent Diary Measure (n = 90)	Diary Mean (SD)	Diary Median	Correlation Coefficient*
• On how many days in the last 3 months did you have any headache? (n = 88)	31.64 (28.72)	20.00	• Total days with headache (n = 92) • Total No. of headaches	40.83† (33.28) 23.32† (19.70)	30.81 18.79	0.88 0.50
• On a scale from 0-10, on average how painful were these headaches? (0 is no pain at all and 10 is pain as bad as it can be) (n = 86)	4.85 (1.94)	5.00	• Total days with migraine headache† • Average pain intensity of all headaches • Average pain intensity for migraine headaches‡ (n = 64)	4.79 (7.74)‡ 4.60§ (1.48) 6.52 (1.63)	2.00 4.84 6.60	— 0.68 —
• On how many days in the last 3 months did you miss work or school because of your headaches? (n = 90)	0.89 (1.67)	0.00	• No. of full missed workdays	0.57§ (1.40)	0.00	0.45
• How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (n = 90)	2.64 (5.47)	0.00	• Days missed work for all or part of day • Days productivity was reduced by half or more • Sum of reduced productivity on headache days	2.31† (5.95) 2.52 (4.40) 3.33§ (5.12)	0.99 0.99 1.38	0.50 0.47 0.56
• On how many days in the last 3 months did you not do household work because of your headaches? (n = 90)	2.78 (5.48)	0.00	• No. of full missed chore days • No. of days missed household work for all or part of the day	0.78† (1.70) 6.73† (8.30)	0.00 3.96	0.36 0.41
• How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (n = 90)	5.39 (8.88)	2.00	• Days productivity was reduced by half or more • Sum of reduced productivity on headache days	5.74 (8.29) 5.78§ (6.80)	2.97 3.56	0.60 0.66
• Composite item combining missed days of household work (MISCHORE) and reduced productivity in the household (n = 94)	8.17 (12.58)	3.50	• Composite item combining No. of full days missed chores and No. of days on which household productivity was reduced by half or more	6.52 (9.50)	3.02	0.65
• On how many days in the last 3 months did you miss family, social, or leisure activities because of your headaches? (n = 90)	2.28 (3.45)	1.00	• No. of missed leisure days	3.26 (4.37)	1.98	0.47
• MIDAS score (n = 90)	13.98 (19.67)	7.00	• Method 1 (50% + = 1 day)¶ • Method 2 (sum of lost time)¶	20.57† (24.91) 21.42† (24.33)	12.43 13.93	0.66 0.66

* All values are significant at $P < .01$.
 † $P < .01$ for the signed rank test comparing MIDAS and diary mean values.
 ‡ No comparison was made between MIDAS and diary data. MIDAS does not ask specifically about migraine headaches.
 § $P < .05$ for the signed rank test comparing MIDAS and diary mean values.
 ¶ For productivity at work and in household, a day was only counted if productivity was reduced by 50% or more.
 ¶ For productivity at work and in household, the percentage reduction in productivity was summed over all diary days as a fraction.