A Randomized Clinical Trial of Multimodal Therapy and Mulligan's Concept of Manual Therapy for Patients with Chronic Pain Syndrome Caused by Upper Cervical Spine Disorders

Marcin Put[1,*], Juliusz Huber[2], Marek Pieniążek[3], Anna Gądek-Michalska[4] and Andrzej Szczygieł[3]

[1]*Department of Physiotherapy, Medical Center in Nowy Wiśnicz, Poland*

[2]*Department of Pathophysiology of Locomotor Organs University of Medical Sciences in Poznań, Poland*

[3]*Department of Physiotherapy, University School of Physical Education in Cracow, Poland*

[4]*Department of Physiology, Institute of Pharmacology, Polish Academy of Sciences, Poland*

Abstract: *Study Design:* A randomized, parallel-group clinical trial, 2 weeks treatment period with follow-up reassessment after therapy.

Objectives: To compare the relative efficacy of multimodal rehabilitation and Mulligan's concept of manual therapy for patients with chronic neck pain and cervicogenic headache.

Background: Cervicogenic headache and neck pain are the main syndromes caused by upper cervical musculosceletal disorders (C0-C3). According to clinical researches for about 20% of the patients with chronic unilateral headache, the cause is of the cervical origin. Relatively little is known about the efficacy of Mulligan's concept of manual therapy for patients with chronic pain syndrome caused by upper cervical spine disorders.

Methods: Patients (n=104) with chronic pain syndrome caused by upper cervical spine disorders, were randomized into two groups: multimodal therapy (massage, electrotherapy, ultrasound) and Mulligan's concept of manual therapy group. Outcomes: pain intensity (VAS), neck disability index (NDI), range of motion (ROM).

Results: Both groups (multimodal therapy and Mulligan's concept) showed significantly reduced pain and disability, but the effect between groups wasn't significantly superior with either therapy alone. Mulligan's concept of manual therapy showed greater gains in range of motion; extension (p=0.01), left rotation (p=0.01) and right rotation (p=0.03) than the multimodal therapy.

Conclusion: Mulligan's techniques are an effective method in the management of upper cervical spine disorders.

Keywords: Cervicogenic headache, neck pain, mulligan, manual therapy, randomized clinical trial.

1. INTRODUCTION

Chronic pain syndrome is caused by upper cervical spine disorders topographically spread to neck or/and head. The International Association for the Study of Pain (IASP) in its Classification of Chronic Pain offers the following definition of cervical spinal pain: perceived as arising from anywhere within the region bounded superiorly by the superior nuchal line, inferiorly by an imaginary transverse line through the tip of the first thoracic spinous process [21]. The Classification of Chronic Pain allows for a subdivision of cervical spinal pain (neck pain) into upper cervical spine pain and lower cervical pain. Neck pain can be divided into upper cervical and lower cervical by a transverse line through C4. Pain referred from a source in the neck and perceived in one or more regions of the head is a common condition frequently encountered by physiotherapists in clinical practice, this entity is known as cervicogenic headache [7]. Cervicogenic headache has been classified by the International Headache Society (HIS) and accounts about 20% of all chronic and recurrent headaches. Patients with chronic cervicogenic headache experience considerable restriction of daily function, limitation of social participation and emotional distress [8]. Headache can arise from a variety of structures of the cervical spine, including the zygapophyseal joints between occiput-C3 [2, 9]. Some headache specialists promoted cervicogenic headache as a distinctive entity that could be diagnosed on the basis of particular set of conventional rules [1]. Those features didn't involve abnormalities of joints detected by manual examination. In clinical practice symptoms of cervicogenic headache usually include unilateral head pain combined with neck pain and restriction in the range of motion. Despite the IHS classification, diagnosis of that syndrome is difficult because up to 70% of patients with frequent intermittent headache report accompanying neck pain, and neck pain alone is a commonly reported problem that

*Address correspondence to this author at the Department of Physiotherapy, Medical Center in Nowy Wiśnicz, 32-720 Nowy Wiśnicz, Podzamcze 4; Tel: +48146128792; Fax: +48146128792; E-mail: marcin_put@op.pl

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has affected 70% of individuals at some time in their lives [6].

Manual therapy is a commonly used treatment for chronic neck pain. Some studies assessed the outcomes of manipulation immediately after treatment in these cases manipulation alone, utilizing one session, consistently showed evidence of no benefit when compare with a control or comparison group [4]. Other have conduced 1 week or 3 weeks, others have conducted longer follow-up [11]. Systematic reviews found no evidence of benefit from manipulative therapy or cervical mobilization for chronic neck pain [12]. One trial with strong methodological quality and large sample size found that manual therapy was beneficial in reducing cervicogenic headache and neck pain [17]. One trial showed for chronic neck pain, that the use of strengthening exercise, whether in combination with spinal manipulation or in the form of a high – technology MedX program, appeared to be more beneficial to patients with chronic neck pain than the use of spinal manipulation alone [3].

Mulligan, using ideas based on earlier founders of manual therapy, has proposed his own techniques of therapy – mobilisations with movement (MWMS) in the extremities and natural apophyseal glides (NAGS) and sustained natural apophyseal glides (SNAGS) [22]. The therapist applies accessory movements and the patient generates active physiological movements. The main basic principles are well-established: During assessment the therapist will identify one or more comparable signs as described by Maitland [5]. These signs may be a loss of joint movement, pain associated with movement, or pain associated with specific functional activities. A passive accessory joint mobilisation is applied following the principles of Kaltenborn [15]. The therapist must continuously monitor the patient's reaction to ensure no pain is recreated. The therapist investigates various combinations of parallel or perpendicular glides to find the correct treatment plane and grade of movement.

The Mulligan concept is frequently used in clinical practice but there is limited evidence for its effectiveness and there is only one clinical trial that has investigated this techniques for the treatment of disorders of the upper cervical spine. Hall *et al*. [13] advocated limitation of cervical flexion-rotation test (FRT) and this had been described by Dvorak *et al*. [10], as one of inclusion criteria. Hall *et al*. in placebo-controlled trials focused on subjects with positive flexion-rotation test and restriction greater than 10°, his study proofed the efficacy of the C1-C2 self – SNAG in reducing cervicogenic headache symptoms sustained over a 1-year period. Theoretically FRT allows one to examine C1-C2: the authors of these researches concentrated only on C1-C2 dysfunctions of the cervical spine. Therefore, the purpose of this study was to compare the relative efficacy of multimodal rehabilitation and Mulligan's concept of manual therapy for patients with chronic neck pain and cervicogenic headache.

2. METHODS

2.1. Study Design

This prospective, randomized, parallel-group clinical trial was performed with unblinded treatment. The treatment period was 2 weeks with follow-up reassessment after therapy. This trial was conducted in the Medical Outcome Center of Rehabilitation in Nowy Wiśnicz (south of Poland). The study was approved by the local Bioethics Commission in Cracow. All patients volunteered and gave written informed consent before entering the study.

2.2. Patients

Subjects were recruited to the study during their first visit to the Medical center. Altogether, 104 patients with chronic pain syndrome caused by upper cervical spine disorders, were randomized into two groups: conservative therapy (T) and Mulligan's concept of manual therapy group (M). Patients 34 to 65 years of age who had a primary problem of mechanical neck disorder (C0-C3) manifested by neck pain or cervicogenic headache were screened by clinicians for suitability according to inclusion and exclusion criteria shown in Table **1**. Diagnostic criteria for that study were

Table 1: Inclusion and Exclusion Criteria for Subjects with Upper Cervical Spine Disorder C0-C3

Inclusion Criteria	Excllusion Criteria
Aged 34-65 years old	Headache not of cervical source
Pain that could be reproduced by neck movement Neck stiffness and/or pain	Physiotherapy or manual therapy treatment in the past 3 months
Referred pain according C0-C3 (neck and/or head)	Headache with autonomic involvement, dizziness or visual disturbance
Symptoms for the past 3 months lasting at least one per week	Whiplash and other injures
	General contraindications for physiotherapy and manual therapy

based on the guidelines of the International Association for the Study of Pain (IASP) and International Headache Society (IHS).

2.3. Randomization

Eligible patients were randomized to one of the two treatment arms on basis of a computer-generator. Before randomization, the group allocation scheme was concealed from researchers and patients. A flow chart indicating flow of participants through each stage of the study is shown in Figure **1**.

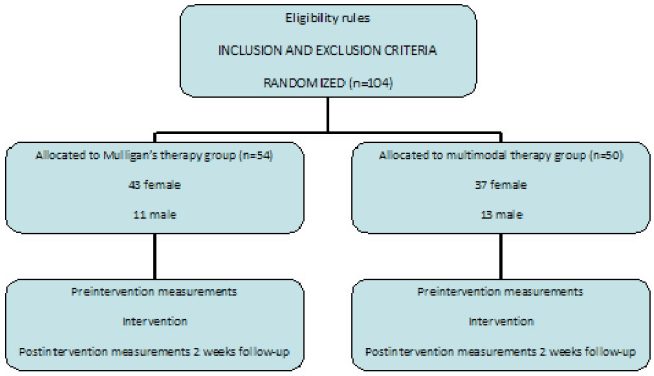

Figure 1: Flow of participants through the study.

Interventions. To balance time and attention, all the patients attended 10 visits during the two week therapy period, materials were collected over a 2-year study period.

2.3.1. Mulligan's Therapy Group (M)

At each visit, patients underwent treatment by one of two physiotherapists qualified in the "Mulligan concept". The subjects in the M group were mobilized (10 visits) with natural apophyseal glides (Figure **2**) and sustained natural apophyseal glides (SNAGS). Subjects were given 10 repetition of each technique per day of therapy according to the guidelines of the Mulligan concept (duration time of mobilization 10 s., 10 repetitions of each technique). The subjects in the M group were mobilized (10 visits) with natural apophyseal glides (Figure **2**) and sustained natural apophyseal glides (SNAGS). Subjects were given 10 repetition of each technique per day of therapy according to the guidelines of the Mulligan concept (duration time of mobilization 10s., 10 repetitions of each technique).

Figure 2: Example of the natural apophyseal glides, technique NAGS (C3-C4).

2.3.2. Multimodal Treatment Group (T)

Patients in the T group received the multimodal treatment combination of massage, electrotherapy and ultrasound on the cervical spine regions. The massage protocol permitted a variety of commonly used clinical massage techniques (duration time 20 minutes) and allowed massage therapists to make typical self-care recommendations. Electrotherapy used uses a low current for its analgesic (Diadynamic, duration time 10 minutes). Individuals in the group T received also, ultrasound therapy, down to C1, duration time 7 minutes, intensity 0,4 W/cm^2.

2.4. Outcome Measurements

Outcomes were measured twice, once at baseline and then after two weeks treatment. The primary outcome was a change in headache and/or neck pain intensity. Pain felt by patients was rated on a 100 point visual analogue scale (VAS): from 0 (no symptoms) to 100 (highest severity of pain). The second outcomes were neck pain and cervicogenic headache related disability and symptoms. The Neck Disability Index (NDI), a 10-item (0 to 50 points) questionnaire that has high internal consistency and test-retest reliability, was used to measure neck-related disability and convergent correlation with the pain visual analogue scale. The passive mobility of cervical spine was the third outcome. The amount of flexion, extension and rotation were measured using a Cervical Range of Motion (CROM of The Saunders Group) instrument. The CROM was attached to the center of head, and the individual was stabilized by sitting on a chair. Range of movement was determined by either the onset of pain or resistance of soft tissue. This method of assessment has been shown to have high reliability [19].

2.5. Statistical Analysis

Data analysis was created using STATISTICA Version 9 (StatSoft Inc). Alpha was set at 0.05 for each analysis. The independent variable pain severity (VAS),

Table 2: Results of Pain Evaluation in VAS (0-100 Points), Changing in Neck Disability Index (Score of Questionnaire) as Well as Range of Motion (°) in Two Planes

Outcome	Group M Preintervention		Group T Preintervention		Group M Postintervention		Group T Postintervention		p*
	Mean Value	± SD	Mean Value	± SD	Mean Value	± SD	Mean Value	± SD	
VAS	53.00	13.41	55.24	12.59	17.19	11.96	23.00	13.61	0.309
NDI	21.39	6.43	20.70	6.12	12.06	6.14	12.84	6.08	0.170
Extension	47.44	11.36	47.68	12.60	53.61	8.02	50.94	11.84	**0.019**
Flexion	42.63	9.74	41.28	10.36	46.12	7.76	43.70	9.53	0.218
Left rotation	48.17	10.61	52.00	10.58	54.35	8.22	55.46	9.45	**0.012**
Right rotation	51.83	12.18	51.08	11.43	57.96	6.62	55.56	10.34	**0.031**

*Indicate the statistically significant differences found at variance (ANOVA) with a repeated – measures factor of time (preintervention, two weeks postintervention) and between-subjects factors of groups (Mulligan's therapy, Multimodal treatment).

neck disability index (NDI) and amount of neck movement (CROM) had normal distributions (Shapiro-Wilk test). Equality of variances was checked by adequate tests (Hartley, Bartlett and Cochran). Implementation of above conditions has allowed the analysis of investigative questions. Data were tested for group differences with analysis of variance (ANOVA). In that case it was the linear model with repeated-measures factor of time (preintervention, postintervention) and a between-subjects factor group (Mulligan's therapy group M, multimodal treatment group T). It was used to determine the difference between the two groups in the amount of neck movement, score of pain severity and disability index.

3. RESULTS

Clinical and demographic characteristics were similar among groups at baseline. The loss to follow-up evaluation was 4.5%. Gender distribution in both groups was similar 43 of 54 were female in the Mulligan's therapy group (M) and 37 of 50 were female in the Multimodal treatment group (T). Group means and standard deviations for the patient-rated outcome measures preintervention and follow-up are presented in Table **2**. In both groups pain severity was observed to be significantly reduced VAS (group M $p<0.01$, group T $p<0.01$) mean ± SD are showed in Figure **3**.

In both groups significant benefits to the quality of life were observed measured by neck disability index NDI (group M $p<0.01$, group T $p<0.01$) mean ± SD are showed in Figure **4**. After 2 weeks of treatment significant increases in the range of motion, in all

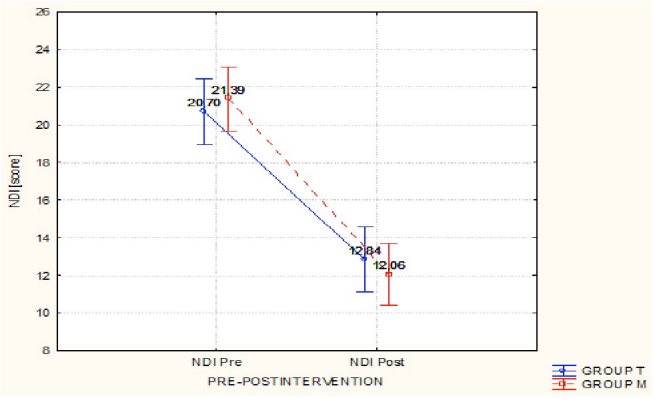

Figure 4: Mean ± SD of NDI pre and postintervention in both groups.

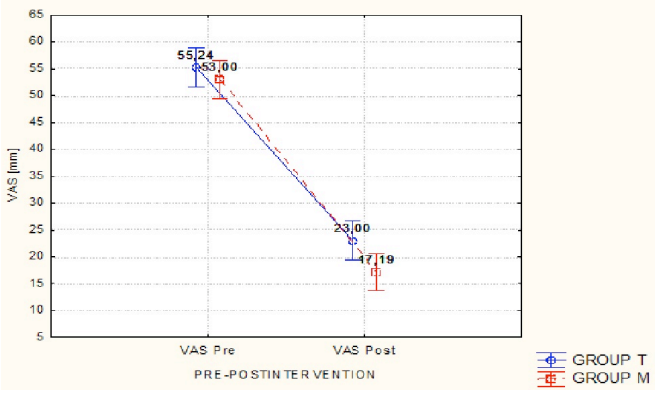

Figure 3: Mean ± SD of pain severity VAS pre and postintervention in both group.

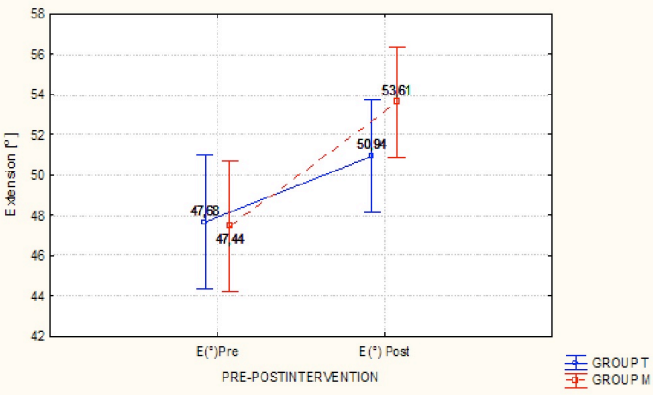

Figure 5: Mean ± SD of extension pre and postintervention in both groups.

directions, were observed (p<0.01) in both groups, the following graphs show mean ± SD: extension Figure **5**, flexion Figure **6**, left rotation Figure **7** and right rotation Figure **8**.

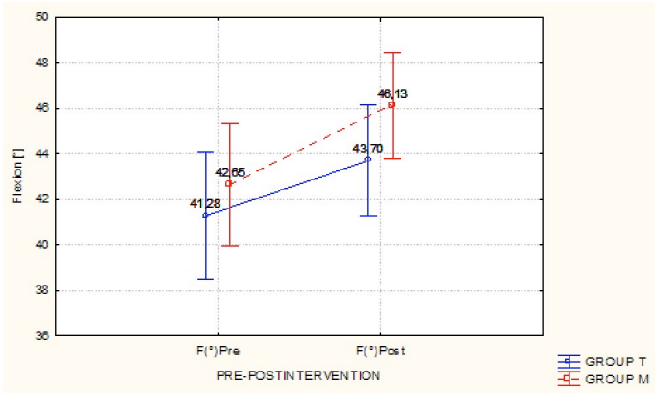

Figure 6: Mean ± SD of flexion pre and postintervention in both groups.

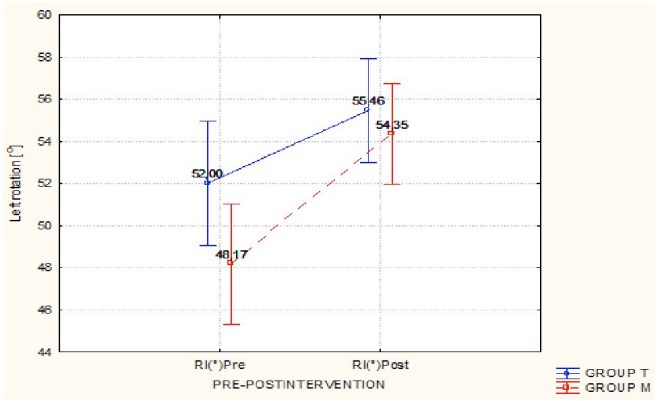

Figure 7: Mean ± SD of left rotation pre and postintervention in both groups.

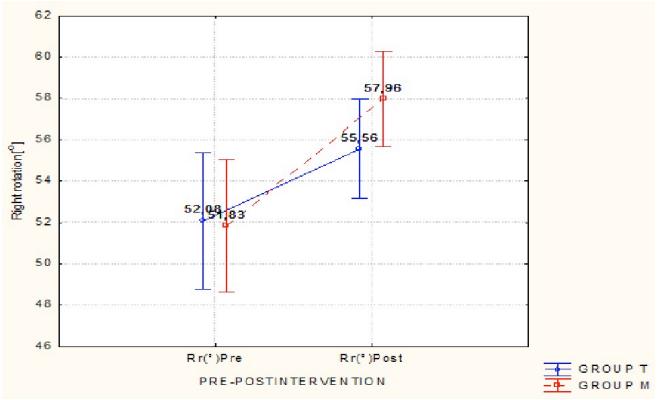

Figure 8: Mean ± SD of right rotation pre and postintervention in both groups.

The above statistical analysis shows that within each seperate group both methods of treatment are effective, but the aim of this study is to compare the treatments across the 2 groups. The analysis of variance (ANOVA) with a repeated – measures factor of time (preintervention, two weeks post intervention) and between-subjects factors of groups (Mulligan's therapy, Multimodal treatment) used to test for change in pain severity VAS showed no statistically significant differences between the groups p=0.30, similar observation was obtained for NDI questionnaire p=0.17. The analysis ANOVA showed that the group treated with Mulligan's therapy demonstrated more improvement in range of motion in extension p=0.01, left rotation p=0.01 and right rotation p=0.03, than the group with Multimodal treatment. The analysis ANOVA showed no significant differences for change of motion in flexion p=0.21 between the groups.

4. DISCUSSION

This study was a clinical trial comparing multimodal therapy and Mulligan's concept of manual therapy for patients with chronic pain syndrome caused by upper cervical spine disorders. Over the term of the study (during the 2 weeks of intervention), both treatments produced substantial improvement in patient-reported symptoms. Our study employed a combination of measures to determine treatment effect. Both methods of treatment are effective, but there are differences depending on the outcome required. This study found that upper cervical spine disorders, when measured by range of motion for both rotations and extension of cervical spine, improved significantly more in subjects treated with Mulligan's therapy than in subjects with Multimodal treatment. Symptoms when measured by pain severity and neck disability index didn't improve significantly in either Mulligan's or Multimodal treatment model. It is recommended that treatment should produce a greater than 50% reduction in pain (ICH). Another has suggested a standard of 50% pain relief, but this is no more than an arbitrary figure [23]. In this study we observed a 68% reduction of pain in group M and 59% in group T. Hall *et al*. evaluated the C1-C2 self – SNAG technique and found a 59% reduction after 4 weeks. Direct comparison to our study is difficult, as their study's outcome measures were based on Headache severity index and its subjects received 1 treatment session by physiotherapist followed by self-treatment. Hall recognized that there are limitations to only using a headache index and self-report of treatment benefits [13]. Both groups resulted in a significant improvement of range of motion parameters in right and left rotation and this agrees with studies suggesting restricted mobility of the atlanto-axial joint as source of pain [12, 14], but outcomes for the present

study didn't use a separate technique of measured segment C1-C2 by flexion – rotation test (FRT) as described Dvorak *et al*. Reduced flexion and extension of the cervical spine in cervicogenic headache was reported by Zito *et al*. [25].

Many different forms of therapy were examined for effectiveness of treatment symptoms arising from the dysfunction of upper cervical spine. Klaber *et al*. compared brief physiotherapy intervention with usual physiotherapy for neck pain patients. Li *et al*. [20]. evaluated effectiveness of spine manipulations, electrotherapy and botulinum toxin injections. Huber *et al*. [16]. Proposed a multimodal program of physiotherapy which consisted of: postisometric relaxation, myofascial mobilization and selected elements of McKenzie therapy. Kanlayanaphotporn *et al*. [18]. Observed immediate effects of the central posteroanterior mobilization technique on pain and range of motion in patients with mechanical neck pain. A number of studies have shown manual therapy to be effective in the management of cervicogenic headache or neck pain [3, 13, 18, 23], but direct comparison to our study cannot be made, as that study's outcome or method measures were not the same.

Compared to researches investigating the mechanisms of the effect of manual therapies [25] our results suggested similar reaction across both methods of therapy. One of the theories of mechanism by which the NAGS or SNAGS techniques my reduce pain symptoms is by the neuromodulation effect of joint mobilization [13]. In the gate control theory, stimulation of mechanoreceptors within the joint structures, surrounding tissues and muscles causes an inhibition of pain at the spinal cord. In addition, descending pain-inhibitory systems (endorphin) may be activated, mediated by areas such as the periaqueductal gray of the midbrain [24]. Hall *et al*. observed that the improvement in rotation range was immediate and suggested that the effect of the C1-C2 self- SNAG technique is more likely related to a neurophysiological change in pain modulation than effects on joint stiffness [13]. However, in our study, the change of range of motion within the M group was significantly larger than the T group, this suggests that Mulligan's techniques of manual therapy (SNAGS, NAGS) have a greater influence on the rebuilding of range of motion. According to group differences in outcome measures across time, the authors consider these differences might be clinically important. In clinical practice a great role is played by the experiences and manual skill of the therapists which allow them to choose more appropriate management of upper cervical disorder.

5. CONCLUSIONS

For cervicogenic headache and chronic pain syndrome caused by upper cervical spine disorders, the use Mulligan's concept of manual therapy appears to be similar to multimodal therapy. Mulligan's techniques of manual therapy (SNAGS, NAGS) have a greater influence on the rebuilding of the range of motion in cervical spine. However, this kind of therapy needs to be evaluated in future studies.

CONFLICT OF INTEREST STATEMENT

No conflict of interest was reported.

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