Original Article

Can postanesthetic cold sensibility test be used as a tool for the efficacy of inferior alveolar nerve block in patients with symptomatic irreversible pulpitis of mandibular molars? – *In vivo* study

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Abstract

Objectives: The goal of this investigation was to determine the efficiency of a postanesthetic cold test for the detection of pulpal anesthesia to improve diagnostic accuracy.

Materials and Methods: Fifty-two participants who showed symptomatic irreversible pulpitis on the mandibular first molar, aged from 18 to 65 years, were given inferior alveolar nerve block (IANB), and subjective anesthetic symptoms were seen after 15 min and were finally assigned for studies. To determine the effectiveness of a postanesthetic cold test for the detection of pulpal anesthesia, the target tooth was separated and Endo-Frost was utilized to conduct a postanesthetic cold sensibility test and was compared to the gold standard test, painful or painless sensation during actual root canal therapy. Of 52 participants, 9 had a positive response to the postanesthetic cold test and 43 had a negative response; 10 responded positively to the gold standard test, whereas 42 gave negative results.

Results: The postanesthetic cold sensibility test can diagnose the effectiveness of pulp anesthesia showing a sensitivity of 80%, specificity of 97.62%, positive likelihood ratio of 33.6, negative likelihood ratio of 0.2, positive predictive value of 88.89%, negative predictive value of 95.35%, accuracy of 94.23%, and Youden's index of 0.78.

Conclusions: The postanesthetic cold sensibility test can be used as a tool for the efficiency of IANB before starting root canal therapy to minimize pain and anxiety in patients.

Keywords: Anesthesia; cryotherapy; endodontics; mandibular nerve; pain; pulpitis

INTRODUCTION

Pain associated with root canal therapy is a primary cause of worry for patients and a major issue for dentists, discouraging individuals from seeking dental care. Local anesthetics are necessary for successful endodontic therapy, with special significance for the treatment of painful, chronically inflammatory, or necrotic teeth.[1] However, administering a local anesthetic solution through regional block injections does not always result in sufficient dental pulp anesthesia.[2] This may cause distress for both the patient and the operator.

In mandibular teeth, pulpal anesthesia, which is the keystone for successful root canal treatment (RCT), is more difficult to obtain than in maxillary teeth.[3] Inferior alveolar nerve block (IANB) is the most frequent approach for attaining pulpal anesthesia in RCT of mandibular molars, but it shows

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a high failure rate.[4] A previous study found that anesthetic failure was seen in above 70% of patients with mandibular molars having an IANB.[5] In mandibular posterior teeth, the treatment of irreversible pulpitis shows a worse success rate than that of reversible pulpitis.[6] Inflamed pulp and periapical tissues have an acidic pH, causing local anesthesia to create local anesthetic salt and become a stable product, further lowering anesthetic efficacy at the affected region.[7]

Unexpected pain can be uncomfortable and distressing during and after endodontic therapy operations. Hence, to measure the anesthetic efficacy level in patients before starting treatment is therefore critical. Most dentists consider lip and tongue edge numbness to measure the IANB anesthetic efficacy. However, previous research discovered that 84% of patients who had acute pain previous to therapy still experienced painful treatment, even after receiving symptoms of lip–tongue numbness.[8] Currently, for determining the anesthetic level, no gold-standard method is available. However, different pulp sensitivity (SN) tests, such as thermal tests (cold and heat) and the electric pulp test (EPT) have been utilized for this purpose. Methods of delivery for heat tests are warm gutta-percha, warm or hot water on a tooth isolated with a rubber dam, or with heat carrier; and methods used for cold tests are ice sticks, dichlorodifluoromethane (DDM), ethyl chloride, carbon dioxide snow and 1,1,1,2-tetrafluoroethane (TFE), commonly referred as Green Endo-Ice and Endo-Frost.

Studies showed that the cold test is simpler and more accurate than electric and heat tests for detecting pulpal anesthesia.[9,10] Furthermore, cold testing is less expensive than pulse oximetry and laser Doppler flowmetry. Ethyl chloride, Green Endo-Ice, DDM, and Endo-Frost have temperatures of around −10°C, −26°C, −50°C, and −50°C, respectively.[11,12] Green Endo-Ice was previously utilized as a cold test in studies and demonstrated, specificity (SP), positive predictive value (PPV), and negative predictive value (NPV) of 0.58, 0.76, 0.88, and 0.38, respectively.[13] Since alternative cold tests are unavailable owing to environmental risks or manipulation challenges, Endo-Frost was used as the cold test in this investigation.

The aim of this investigation was to evaluate the efficacy of a postanesthetic cold test for the detection of pulp anesthesia to improve diagnostic accuracy and to compute the SN, SP, positive likelihood ratio (LR+), negative likelihood ratio (LR−), PPV, NPV, accuracy, and Youden's index. According to the null hypothesis, the outcomes of the postanesthetic cold test and the gold standard test, which involved actual access cavity preparation and pulp extirpation, did not vary significantly.

MATERIALS AND METHODS

This study of diagnostic accuracy was conducted according to the STARD guidance.[14] The investigation protocol had been registered on Clinical Trial Registry India (CTRI) as registration no. CTRI/2024/03/063842 and by Institutional Review Board of Saraswati–Dhanwantari Dental College and Hospital, Postgraduate and Research Institute, Parbhani, India, with Protocol No. SDDCH/Admin/182/2024. The research was carried out at the department of conservative dentistry and endodontics, between March 09, 2024 and March 18, 2024. Seventy-four adult patients participated in the study; the study protocol and treatment procedure were explained to them. Every participant had read and signed the informed consent form. Participants with acute symptomatic pain and symptomatic irreversible pulpitis (SIP) on the mandibular first molar, aged 18–65, were included.

Pregnant women, teeth with crowns, unrestorable tooth structure, periodontitis, root resorption, narrow pulp chambers and crack teeth, patients having uncontrollable diabetes or hypertension, and patients having adverse reactions to local anesthetics or a history of taking analgesic drugs before treatment were all exclusion criteria. Furthermore, the study excluded patients which not react to cold tests before giving an IANB, had radiological periapical pathosis, or had a nonvital tooth that was seen while accessing cavity opening.

A cold test was used to assess the initial diagnostic and pulp sensitivities before starting treatment and before providing local anesthesia. Adjacent teeth isolation was done with cotton rolls, and a cotton pellet #2 sprayed with Endo-Frost (ROEKO Endo-Frost, Coltene Whaledent) (isobutane 10%–20%, butane 30%–50%, and propane 30%–50%) was utilized for 5 s to the middle third of the buccal surface of the symptomatic and neighboring teeth. The Heft-Parker Visual Analogue Scale (VAS) [Figure 1] has been employed to assess participants' responses to tooth pain. If the response to cold tests was more severe and prolonged than the opposite molar teeth, the condition was categorized as SIP. Fifty-seven participants were enrolled for the trial and given an IANB with 1.8 mL of 2% lidocaine and 1:100,000 adrenaline through a 27G needle over 20 s. After 15 min, all patients were asked if they had tongue and lip numbness. Fifty-two participants with tongue and lip numbness, who showed no response to picking stimuli were identified as an IANB success and ultimately assigned

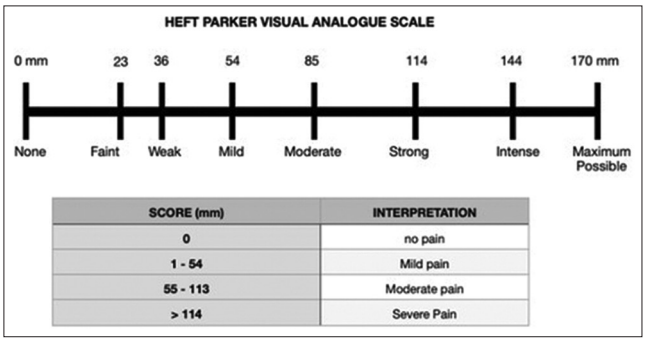

Figure 1: Heft–Parker Visual Analog Scale

to this research. After 15 min of IANB, patients who did not experience tongue and lip numbness and showed a painful reaction to the picking stimuli were not included ($n = 5$).

Using the statistical model by Chavarría-Bolaños *et al*., the sample size was calculated with a type I error of 0.05 (significance of 95%), $Z\alpha = 1.96$, $Z\beta = 0.84$, and 80% statistical power. According to a previous study, the cold test ($P2 = 0.84$) and the gold standard test ($P1 = 1.0$) had the average SN percentage value, or P value.[15] The targeted sample size was 44 participants. However, 52 participants took part in the trial.

$$n = \frac{\left[Z_{\alpha} / 2\sqrt{2P(1-P)} + Z_{\beta}\sqrt{P1(1-P1)+P2(1-P2)} \right]^2}{(P1-P2)^2}$$

Following 15 minutes of soft-tissue anesthesia confirmation, the tooth of interest was separated with a rubber dam, and the pulpal anesthetic success or failure was determined by a postanesthetic cold test using Endo-Frost and the results were documented.

The carious tooth structure was removed with a novel high-speed diamond round bur #4 and access cavities were finished with an Endo *Z* bur by deroofing and removing the pulpal tissue. The pain sensation felt during access cavity opening and pulp extirpation was categorized as positive (pain) or negative (no pain), and this result was considered as the gold standard results. Individuals in pain were given additional local anesthetic, and the endodontic process was continued.

Statistical analysis

The Chi-square test has been employed to statistically evaluate patients' positive (painful) and negative (painless) responses to the postanesthetic cold test and gold standard test. The two-tailed Fisher's exact test was used to compare pain responses between female and male participants. The Chi-square test has been utilized to compare pain levels in different age groups. At $P < 0.05$, the outcomes were statistically significant.

There were participants who had false positives (FPs), true negatives (TNs), true positives (TPs), and false negatives (FNs). MedCalc's free online diagnostic test statistical calculator[16] was used to determine the postanesthetic cold test's SN, SP, LR+, LR−, PPV, NPV, and accuracy (AC) with 95% confidence intervals. The Youden index was calculated as: (SP + SN) – 1.

RESULTS

Fifty-two patients were finally considered for the final research process. Patients aged 18–65 years (mean age: 37.038 years) were selected, of which 18 were male and 34 were female. Forty-three showed negative (painless) and 9 showed positive (painful) responses to the cold test, whereas 42 showed negative (painless) and 10 showed positive (painful) responses to the gold standard test (access cavity opening and pulp extirpation). The study process is mentioned in Figure 2.

The failure rate for IANB demonstrated by the postanesthetic cold test was 17.3%, while the gold standard test was 26.9%. The two-tailed Fisher's exact test revealed that there was no statistically significant difference ($P > 0.05$) between the gold standard test and the postanesthetic cold test findings for either male or female patients [Table 1]. The Chi-square test revealed that there was no statistically significant difference ($P > 0.05$) between the findings of the different age groups [Table 2]. The postanesthetic cold test and the gold standard test showed a significant connection ($P < 0.05$) with a $P < 0.00001$, according to the Chi-square test. These data led to the acceptance of the null hypothesis for this study.

The responses for TP, TN, FP, and FN were 8, 41, 1, and 2, respectively. A positive result from a postanesthetic cold test and a gold standard test is referred to as a TP. A negative result from a postanesthetic cold test and a gold standard test is referred to as a TN. FP is the term used to describe a positive response to the postanesthetic cold test but a negative result to the gold standard test. FNs occur when there is a positive result on the gold standard test but a negative result on the postanesthetic cold test.

The postanesthetic cold test diagnostic values with 95% confidence intervals, reveal a SN of 80.00% (44.39%–97.48%), a SP of 97.62% (87.43%–99.94%), a LR+ of 33.60 (4.73–238.82), and a LR− of 0.20 (0.06–0.71) and at the disease prevalence of 19.23% (9.63%–32.53%), PPV, NPV, and accuracy of the postanesthetic cold test were 88.89% (52.95%–98.27%), 95.35% (85.57%–98.61%), and 94.23% (84.05%–98.79%), respectively. SN refers to a test's capacity to appropriately categorize a person as diseased. SN "is (TP)/(TP + FN). The SP of a test is its capacity to correctly classify a person as disease-free. SP is (TN)/

Table 1: A comparison of male and female patient's pain perceptions to the postanesthetic cold test and gold standard test, as well as the overall percentage of pulpal anesthetic failure and success

Gender	Patient's response			
	Cold test		Gold standard test (procedure test)	
	Pain, *n* (%)	No pain, *n* (%)	Pain, *n* (%)	No pain, *n* (%)
Males (*n*=18/34.4%)	3 (17)	15 (83)	2 (11)	16 (89)
Females (*n*=34/65.4%)	6 (18)	28 (82)	8 (24)	26 (76)
Total (*n*=52)	9 (17.3)	43 (82.7)	10 (26.9)	42 (73.1)
*P**	1		0.46	

*Two-tailed Fisher's exact test (difference $P<0.05$)

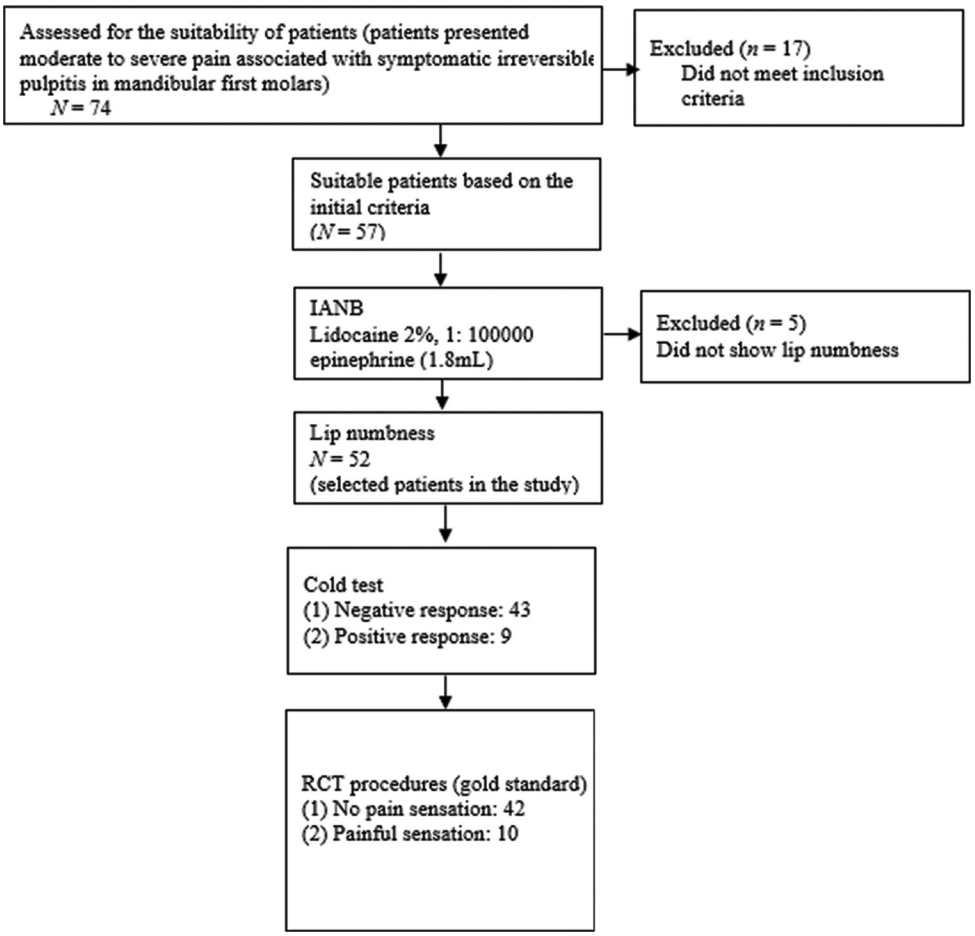

Figure 2: A flowchart of the study process. IANB: Inferior alveolar nerve block

Table 2: Comparison of pain perception of different age group patients to postanesthetic cold test and gold standard test

Age (years)	Patient's response			
	Cold test		Gold standard test (procedure test)	
	Pain, *n* (%)	No pain, *n* (%)	Pain, *n* (%)	No pain, *n* (%)
18–25 (10)	2 (1.73); 0.04	8 (8.27); 0.01	4 (1.92); 2.24	6 (8.08); 0.53
26–35 (20)	3 (3.46); 0.06	17 (16.54); 0.01	2 (3.85); 0.89	18 (16.15); 0.21
36–45 (10)	1 (1.73); 0.31	9 (8.27); 0.06	1 (1.92); 0.44	9 (8.08); 0.11
46–55 (6)	2 (1.04); 0.89	4 (4.96); 0.19	2 (1.15); 0.62	4 (4.85); 0.15
56–65 (6)	1 (1.04); 0.00	5 (4.96); 0.00	1 (1.15); 0.02	5 (4.85); 0.00
Total (52)	9	43	10	42
Chi-square test	1.5766		5.2165	
P	0.812997		0.265795	

(TN + FP).[17] The percentage of patients with a positive test result who also have the condition" is known as the PPV. PPV= (TP)/(TP + FP). The percentage of patients who have a negative test result but do not actually have the disease is known as the NPV. NPV = (TNs)/(FN + TN).[17] Using likelihood ratios, providers can ascertain how much the implementation of a particular test will change the probability. An LR+ is the probability that a positive test would be expected in a patient divided by the probability that a positive test would be expected in a patient without a disease. LR+ = SN/(1-SP). A LR− is defined as the probability of a patient testing negative who has a disease divided by the probability of a patient testing negative who does not have a disease. The LR− is computed as (1-SN)/SP.[18] Diagnostic accuracy (effectiveness) is expressed as (TP + TN)/(TP + TN + FP + FN).[19] Values for the diagnostic parametric results are provided at a 95% confidence interval, including the lower and upper bounds.

The Youden's index for the postanesthetic cold test in this study was 0.78. Youden proposed another diagnostic criterion to evaluate the total utility of a dichotomous diagnostic tool.[20] It is the greatest potential effectiveness of a diagnostic test. When a diagnostic tool's Youden's

index is more than 0.5, it satisfies scientific requirements for use.[21] In this study, as Youden's index is more than 0.5, the postanesthetic cold test can be utilized as a standard diagnostic tool.

DISCUSSION

Endodontists have the issue of managing endodontic pain with appropriate anesthetic, particularly while interacting with a "'hot'" tooth. A pulp with irreversible pulpitis, resulting in moderate-to-severe discomfort, is referred to as a hot tooth. It is mostly seen in mandibular molars and the reasons for hot tooth are as follows. First is the anatomical reason, the dense cortical bone hinders anesthetic penetration, also accessory innervation and inferior alveolar nerve fibers crossing the midline may cause anesthetic failure. Second is inflamed tissue and low pH, inflammation of tissue causes a lowering in pH, which limits the quantity of base anesthetics that may permeate the neural membrane, resulting in just a small amount of ionized form of anesthetics being present in the nerve causing anesthetic failure. Third is the altered blood flow, inflammation alters the local tissues' physiology. Peripheral vasodilation is facilitated by inflammatory mediators and thus decreases the concentration of local anesthetics at the site of action, lessens their systemic absorption, and boosts their buffering capacity in inflammatory tissues, all of which expedite their removal. Fourth is tetrodotoxin (TTX)-resistant channels, inflamed tooth pulp increases TTX channel expression, making it more resistant to local anesthetics. In addition, this decreases the voltage-gated sodium channel activation threshold leading to increased Na ion influx across the nerve membrane and failure of anesthesia. Moreover, fifth is the activation of nociceptor, an inflammatory mediator that lowers neuronal stimulation thresholds during inflammation. During inflammation, the cyclooxygenase system produces prostaglandins (PGs). PGs make nerve endings more sensitive to inflammatory mediators such as bradykinin and histamine, leading to increased pain feelings.[22]

Currently, dental practitioners favor IANB anesthesia for painless endodontic treatment of mandibular molar teeth. As previously mentioned, in patients with SIP anesthetic failure is prevalent in mandibular molars. Several studies have indicated that tongue and lip numbness is not a reliable predictor of IANB success in pulpal tissue. The optimal method for detecting pulpal state should be nondestructive, standardized, painless, reproducible, dependable, cost-effective, and easy to use. When the disease was present, a perfect diagnostic test would always be positive; otherwise, it would be negative. Nevertheless, a test's ability to fulfill a clinician's two main diagnostic objectives identifying the presence or absence of disease is compromised by FN or FP results.

Hence, to have an ideal postanesthetic diagnostic test to assess the anesthetic efficacy of dental pulp before endodontic treatment is necessary to avoid painful treatment and further dental fear and anxiety in patients after treatment. Various pulp sensibility tests such as thermal tests (heat and cold stimuli) and EPT have been used for this purpose. Studies show that diagnostic testing with the most accurate method was a cold test.[23,24] As a result of the benefits of cold testing with Endo-Frost, it was chosen to evaluate pulpal anesthesia in this study. DDM refrigerant poses an environmental risk and is no longer accessible commercially. Green Endo-Ice, or TFE, has taken its place. Green Endo-Ice has a temperature of −26.2°C and has been used in past studies. Endo-Frost, also known as Endo-Ice F (Coltene/Whaledent), has a temperature of −50°C, the lowest of any commercially available substance up to this point. It is composed of 30%–50% propane, 30%–50% butane, and 10%–20% isobutane. Endo-Ice F, also known as Endo-Frost, and Green Endo-Ice show similar temperature-lowering effects in the pulp chamber.[25] Hence, Endo-Frost is been used in this study. The study results show that postanesthetic cold tests have SN, SP, LR+, LR−, PPV, NPV, accuracy, and Youden's index of 80%, 97.62%, 33.6, 0.2, 88.89%, 95.35%, 94.23%, and 0.78, which is enough to consider postanesthetic cold test for pulpal anesthetic efficacy of IANB. Cold test elicits peripherally located A-delta fiber and cannot activate the deeper C fiber of the pulp, due to this, sometimes FN results can be obtained.

The cold sensibility test should be used as a routine diagnostic tool for detecting pulp sensibility. El Sayed and Gaballah (2021)[21] utilized Coltene/Whaledent Inc., OH, USA's Green Endo-Ice refrigerant (−26.2°C) for the cold test; the results showed that the accuracy, SN, SP, PPV, and NPV were, in that order, 87%, 91%, 93%, 84%, and 89%. Hsiao-Wu *et al*.[13] utilized TFE, commonly referred to as Green Endo-Ice (Hygenic Corp®, Akron, OH) at −26.2°C, exhibits the following values: 58%, 76%, 88%, and 38% for SN, SP, PPV, and NPV respectively. With SN, SP, PPV, NPV, and accuracy of 80%, 97.62%, 88.89%, 95.35%, and 94.23%, respectively, Endo-Frost (−50°C) was utilized for cold testing in the current investigation. The current study shows better results because Endo-Frost was utilized as a cold test which has a lower temperature compared to other cold tests.

Hence, in clinical practice after having subjective symptoms of anesthesia, a cold test can be used as an approach to determine the efficiency of pulpal anesthesia, if pain to postanesthetic cold test was noted various approaches using different anesthetic solutions, concentrations, and techniques for endodontic anesthesia is to be carried out. Furthermore, for various systemic conditions such as diabetes and hypertension, the cold sensibility test shows better results than other pulp sensibility tests.[26] While

the postendodontic pain is managed by the corticosteroid and nonsteroidal anti-inflammatory drugs.[27,28] Cold pulp vitality test is one of the criteria for a successful restoration for pulp vitality confirmation.[29]

The shortcomings of this investigation were its limited sample size and conduct in a specific geographic region, thus the results may not be generalizable to broader populations. The time limit of the procedure was not standardized, which may have an impact on the results. Individuals' emotional responses to pain, as well as therapeutic procedures, may influence the outcome. To overcome the limitations of this study, more research is needed, as well as to investigate various anesthetic techniques and solutions.

CONCLUSIONS

Based on the results of this investigation, even with signs and symptoms of soft-tissue anesthesia, 26.9% of patients fail to achieve profound pulpal anesthesia after IANB of mandibular first molars using SIP. The postanesthetic cold sensibility test with Endo-Frost has an SN (80%), SP (97.62%), LR+ (33.6), LR− (0.2), PPV (88.89%), LPV (95.35%), accuracy (94.23%), and Youden's index (0.78) which are sufficient to predict pulpal anesthesia efficacy. In patients suffering from symptomatic irreversible pulpitis, soft-tissue anesthetic signs and symptoms of tongue and lip numbness, along with the postanesthetic cold sensibility test are effective for the detection of pulpal anesthesia in mandibular first molar before starting root canal therapy.

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Conflicts of interest
There are no conflicts of interest.

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