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HOME USED, PATIENT SELF-MANAGED, BRAIN-COMPUTER INTERFACE FOR TREATMENT OF CENTRAL NEUROPATHIC PAIN IN SPINAL CORD INJURY: FEASIBILITY STUDY

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ABSTRACT: Central Neuropathic Pain (CNP) is a frequent chronic condition in people with spinal cord injury (SCI). In a previous study, we showed that using laboratory brain-computer interface (BCI) technology for neurofeedback training, it is possible to reduce pain in SCI people who suffered from CNP for many years. In this study, we show initial results from 12 people with SCI and CNP who practiced neurofeedback on their own using our portable BCI, consisting of a wearable EEG headset (Emotiv, EPOC, USA) and a computer tablet. Eight participants showed a positive initial response to neurofeedback and seven learned how to use portable BCI on their own at home. In this paper, we present a portable BCI and discuss the main challenges of training lay people, patients and their caregivers, to use a custom designed BCI application at home.

INTRODUCTION

Brain-computer Interface has been a focus of multidisciplinary research for almost two decades, and most of its applications have been designed for patients. Yet with the exception of BCI spellers for nearly locked in people [1] and brain painting BCI [2], there is no reported application of BCI that patients can use at home on their own, though several studies explored priorities of potential BCI home users, including patients with SCI [3] . There are several consumer BCI systems in the research phase or on the market [4], but their applications are mainly for gaming or improving the concentration of the able-bodied population. Furthermore, consumer BCI applications typically do not involve EEG recording during training allowing post hoc analysis, so it is hard to check user's actual performance.

It is reasonable to assume that the main users of consumer BCI systems are people who like technical innovations [4]. The experience of these people might not necessarily be directly transferable to patients who may have a physical or cognitive disability, belong to an older age group and possibly do not share a passion for technical innovations.

With the advent of portable and inexpensive EEG [4], it became possible to organize feasibility pragmatic studies, on a larger number of participants to observe how lay people, with mild to severe physical impairments and with average consumer technical literacy use BCI on their own. Due to the nature of participants, it is equally important to understand the attitude of their caregivers towards an unconventional assistive/rehabilitation device.

In this paper, we present, to the best of our knowledge, the first pragmatic (not directly controlled by a researcher) feasibility study of neurofeedback treatment of SCI patients based on [5], using BCI technology in a home environment. We present the main components of custom-made software for portable BCI and the effect of training on pain. The main focus of the paper is however patients' experience of using the BCI system on their own.

MATERIALS AND METHODS

Patients: Twelve patients (54±9, 2F) with chronic SCI and with previously diagnosed CNP were included in the study (Table 1). Paraplegic and tetraplegic adult patients, with complete or incomplete injury, were included in the study. Americal Spinal Injury Association (ASIA) impairment scale level A-D corresponds to the different levels of severity of motor and sensory impairments [6]. The level of injury C (cervical) correspond to tetraplegia while T (thoracic) and L (lumbar) to paraplegia (Table 1).

Exclusion criteria were the patients' inability to understand the task, epilepsy or any self-reported mental health problem. Minimum computer literacy and Internet access were required. Patients were asked to try not to change their regular pain medications (pregabalin or amitryptiline) throughout the study as this could influence the outcome. Only patients with CNP equal to or greater than 4 on the Visual Numerical Scale VNS (0=no pain, 10=worst pain imaginable) were included in the study. All patients signed the informed consent. Ethical permission was obtained from the local

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national healthcare service Ethical Committee.

BCI software: Custom-made software was created in visual C++.net. It consisted of three main parts: raw EEG data collected through a wireless communication with the headset, signal processing following the algorithm described in [5], and a graphical user interface. The graphical user interface had three screens (Fig.1). It consisted of the main screen for neurofeedback training, pain diary screen and screen for setting system parameres. Control buttons on the main screen were color coded to enable persons with mild vision problems to easily recognize different commands.

Electronic pain diary (in VNS units) had to be filled out before the start of training and before logging off. EEG signal was recorded during training and the experimenter could remotely access patients' EEG to upload the data if patients allowed access.

Neurofeedback training: Prior to taking portable BCI home for neurofeedback training, patients had up to four 30 min long neurofeedback pre-training sessions using a laboratory device usbamp (Guger Technologies, Austria) following protocol [5]. The EEG sampling frequency was 256 samples/s, the right ear served as a reference and the left ear as a ground. The impedance was set prior to the EEG recording to a value under 5kΩ. At the very beginning, a 2 min EEG was recorded to serve as a baseline for subsequent neurofeedback. Training was provided from C4, located over the primary motor cortex, which is an area typically targeted by neuromodulatory treatments of CNP [7]. Patients were presented with a graphical user interface (GUI) showing three bars. The bars changed size and color, to either red or green (Fig .2). Patients were instructed to "do whatever necessary to make bars green". Three bars represented the theta, alpha and higher beta (20-30 Hz) band relative power. Relative power was calculated as a power of a chosen frequency band divided by a power in 2-30 Hz band. The bars representing theta and beta band had a green color when the relative power was 10% or more, below the baseline value, otherwise, they had a red color. A bar representing the alpha band had a green color when the power was 10% or more, above the baseline value, otherwise was red. Chosen features were based on our study defining markers of CNP [8]. Four sessions for the initial assessment of the effect of neurofeedback on pain were chosen based on the literature [9]. A subset of patients, who reported a reduction in pain of at least a 1 grade on the VNS and in addition reported sensations such as tingling or pleasant heat during neurofeedback pre-training, were included in the 2nd part of the study, using BCI at home. In the previous study [5] it was noticed that these sensations often precede the reduction of pain. Because patients were not informed about these sensations prior to training, this served as a quick "anti-placebo" test.

Questionnaires and Communication with Patients:

Upon arrival at the laboratory, the purpose of the study was explained to patients. A semi-structured interview was either audio recorded or notes were taken by two experimenters. After briefly demonstrating how the BCI system works, on the first session, they were asked to complete a custom-made questionnaire on the "Perceived usefulness of a device for a home-based treatment of central neuropathic pain", a validated questionnaires "Brief Pain Inventory" [10] and "Neuropathic pain symptoms inventory" [11]. Patients were contacted after one week and after one month by either phone, SMS, email or Skype, and some visited the laboratory. Volunteers who completed the study have been asked to finally complete the "Brief Pain Inventory" and a custom-made questionnaire: "Neuropathic system users questionnaire".

Educating patients to use portable BCI: on each session, following neurofeedback pre-training with usbamp, patients and their caregivers were trained to use the EPOC headset and a custom made software. Tuition consisted of three parts: training to adequately moisten the electrodes and to place the headset on the right location of the head, training to use Emotiv proprietary software to check the electrode-skin impedance and training to use a custom designed BCI software. The headset was tilted back compared to the recommended use by Emotiv, so that the electrode locations F3 and F4 were located approximately at locations C3 and C4 (or for smaller heads between C3 and C1 and between C4 and C2). To find the right location, patients were instructed to imagine a vertical line coming from their ears and to place the device in such a way that one long EEG electrode is placed just to the front of that line and the other long electrode just to the back, as shown in Fig. 2. The electrode just behind the vertical red line was used for neurofeedback training. A photo of a patient wearing the headset was also taken on the patient's smartphone.

Following this, patients were taught how to use a GUI to check the color-coded electrode impedance (Emotiv proprietary software). They were instructed to add saline and press the electrodes gently, aiming for the green colour to appear on all electrodes. The electrode from which neurofeedback training was provided was labeled with a sticker so that patients could be sure that it always had good contact. In order to assure a good tight contact between a headset and the head, in particular, a good contact of the reference electrodes, patients were given an elastic band to wrap around the head to prevent the headset from slipping. EPOC EEG has a sampling frequency of 128 samples/s and two references at P3 and P4 (in the case of this application they were placed over parietal lobes close to ears) for CMS/DRL noise cancellation. As the last step, patients and caregivers were trained to use the custom-made software. Before they got a portable BCI to take home, they had to demonstrate to the experimenter that they were capable of doing all three steps on their own (placing EEG headset, impedance check, neurofeedback training). Two manuals were provided to patients: a proprietary EPOC headset manual and a custom-made manual explaining how to correctly place the headset

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for the purpose of neurofeedback training and how to use the custom-made software. Patients were offered as many sessions as needed to learn to use the portable BCI. Neurofeedback protocol with portable BCI followed the same rules as the one with 'usbamp', previously described. They were asked to use BCI for three months, at least once a week and were offered to keep it following that period.

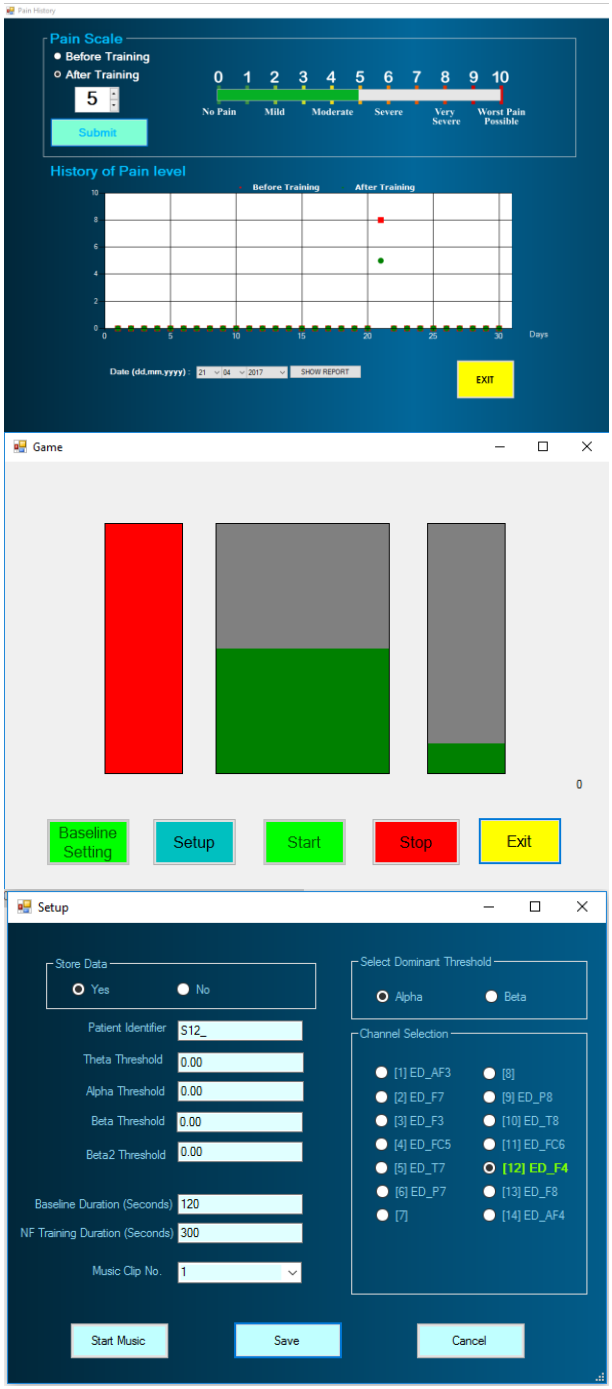

Figure 1. Main screens. Upper: Pain diary; Middle: Neurofeedback GUI; Lower: System parameteres

RESULTS

Information about patients is provided in Table. 1, while information about training is provided in Table. 2. In Table. 2, the first column to the left shows the intensity of pain as measured by VNS for each patient before and after the first few assessment sessions. Column 'Min pain' is the minimum intensity of pain reported while using BCI at home. Column "Nr AS" shows the number of assessment/education sessions, column "Nr SS" shows the number of additional support sessions requested by a patient, after starting to use BCI at home. These sessions were in addition to regular checks-ups after a week and a month. Column "Diff" shows the patient' perceived difficulty of using a portable BCI (1=very easy, 10=extremely difficult), the average value shown in Table. 3. Finally, the last column shows how long patients used the system for. The only person who considered BCI difficult to use (Diff=7) gave up after trying to use it for a month.

Fig. 3 shows one example of EEG Power Spectrum Density (PSD) taken from a home based neurofeedback session of one representative patient. The blue colour represents PSD during 2 min long EEG baseline recording while the red color represents PSD during 5min long neurofeedback sub-session. The patient was successfully reducing theta and higher beta power and to a lesser degree was increasing the power of the alpha band. This example shows that patients can successfully use the system on their own and that they are capable of simultaneously increasing and decreasing EEG power in different frequency bands.

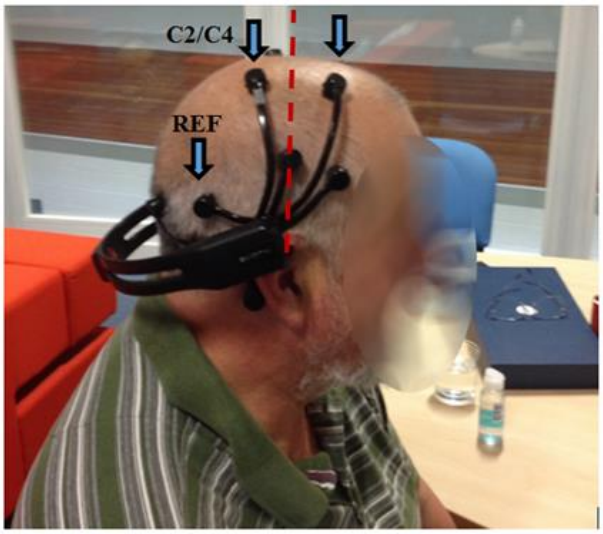

Figure 2. An example of correct placement of the headset. Long EEG electrodes normally placed frontally, tilted to the central area are marked with arrows. A reference electrode in the parietal region is also marked with an arrow. Electrode for neurofeedback training has an approximate location between C2/C4.

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Patient demographic. Seven patients were paraplegic and five were tetraplegic. Three tetraplegic patients had an injury that prevented them from using their hands, so they required a caregiver to help them with using the headset. One of them gave up after the first session, due to ill health, one patient and a caregiver were interested in using BCI but the patient had no response to neurofeedback and one patient had a supportive caregiver and a response to neurofeedback.

Table 1. Information about patients

	Age/gender/	Injury level	ASIA	Years since injury
P1.	62 M	L3/L4	D	9
P2.	51 M	T6/T7	D	7
P3.	56 F	T5	D	3
P4.	64 M	T4	A	7
P5.	66 M	L3	D	5
P6	59 M	C2	B	5
P7.	59 M	C2	A	7
P8.	50 M	C3/C5	D	3
P9.	54 F	T5	A	7
P10.	35 M	C4	D	15
P11.	42 M	C2	A	1
P12.	49 M	T6	B	1

Table 2. Information about pain level and the number of support sessions. Nr AS: the number of assessment and training sessions, Nr SS: number of additional support sessions. Diff: estimated difficulty of using portable BCI.

	Pain before/ after initial assessment	Min pain	Nr AS	Nr SS	Diff	Home use (months)
P1.	10/8	1	2	/	2	10
P2.	7/5	2	1	/	2	7
P3.	7/5	5		4	7	1
P4.	7/5	3	3		3	3
P5.	5/4	4	3		2	3
P6	8/8	8	1	-	-	-
P7.	5/3	2	2		2	2
P8.	5/5	5	3	-	-	-
P9.	5/5	5	2	-	-	-
P10.	5/3	2	2		1	2
P11.	5/5	5	3	-	2	-
P12.	8/4	2	3	1	1	1

Only two out of 9 patients who could use their hands brought a caregiver to the laboratory, to learn how to use BCI so that they could help at home as required, two of these patients lived on their own. All patients had at least a secondary school education. Four patients were employed, three retired and five stopped working after injury. All patients lived in areas within an hour drive of the hospital.

Pain descriptors: Central neuropathic pain was present in all patients below the level of injury and all patients had pain on their feet and below their knees. The pain was described with standard descriptors of CNP i.e. extremely hot (burning) or extremely cold (freezing), stinging or as a tightrope (in patients who also had pain at the level of injury). All patients first started feeling tingling, pleasant warmth and reduction of pain in feet. The effect of neurofeedback training was assessed using the VNS and also the total body area affected by pain. Fig. 4 shows an example of body maps affected by pain before and after 3 months of training, showing that pain was completely reduced in the upper body.

Patients' expectations: Prior to demonstrating a portable BCI, experimenters asked patients about their expectation prompting them to describe the preferred weight, and size of the device and the expected usage pattern. The majority expected a small and robust device that could fit into a handbag. The most frequent questions to the experimenter were, how long should they wear the headset for? Could they do daily activities wearing the headset? And should they use the device constantly? The last question indicates that lay people, in general do not have a good understanding of how BCI works, i.e. that it requires some sort of feedback and that it is used intermittently.

BCI usage pattern: Three patients used the device almost daily while most patients used it at least once a week. Although they were advised to use the device for 30 min, P2 used it much shorter while still reporting benefits. Most patients used the device in the evening when they had more time. Similar to our previous study [5], 5 patients who used BCI reported that they could bring themselves into the 'traning' state without using the device, by simply imagining doing it. For example, a patient who worked in a call center wearing headphones said that he imagined that the headphones were the EEG headset and that helped him to imagine training and experience less pain.

Communication with patients: most patients preferred SMS or the Internet and two used Skype messenger. We offered to all patients video Skype support (the tablet computer had a camera) but only one patient used it. The laboratory in which patients were recruited was situated within the Spinal Injuries Unit, thus four patients preferred coming to the laboratory for a check-up or for additional assistance with BCI. This indicates that people like having personal contact although electronic communication is less time-consuming.

Perceived usefulness of portable BCI: At the end of the first demonstration session patients were asked to answer a set of questions shown in Tables 3 and 4. Table 3 shows perceived usefulness and ease of use of BCI. On average, all patients believed that they could understand the main purpose of the device and that it would not be hard for them and their caregivers to use it. They also showed a strong belief towards the potential usefulness of the device.

Attitude towards using a novel technology: Table 4 showed that all participants had a positive attitude towards novel technologies. There was no stigma about wearing a gadget on the head in front of family and friends. Patients were also asked to choose one or more of the following attributes of a new product which is most important to them when deciding to buy a device: price, aesthetics (looks), size, new features, size of letters

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and symbols, friends and family already having the device, it is novel (only a few people have it), easy to relate to something they already have, technical support. The most frequently selected answers were "price" and "new features", followed by "technical support" and "size".

Technical issues with EEG headset: Three headsets frames broke and two patients asked for replacement sponges for the EEG electrodes. The most frequent issues were loose electrodes falling out from their sockets and difficulty achieving good electrode-skin contact. Occasionally slipping of the headset was reported due to loosening of the frame (after prolonged use) or due to long hair. This was resolved by wrapping an elastic band around the headset.

Technical issues with the custom made software: Patients mostly complained of the small size of a warning message at the end of the baseline EEG recording. Some patients initially forgot to complete to pain diary to allow them to start training or log out. A major problem was that there was no electronic evidence of neurofeedback performance, which could be compared from one day to another.

Other issues affecting the study: The main issue affecting the use of BCI was a change of daily routine, caused by e.g. unrelated health problems, travels, pressure sores which required bed rest, moving home and a change of caregiver. Due to the headset design, it was inevitable that the location of electrode varies from one session to another, possibly influencing its performance. Another factor influencing the study was a negative opinion of a trusted authority such as a general practice doctor (" We do not really know what the device is doing").

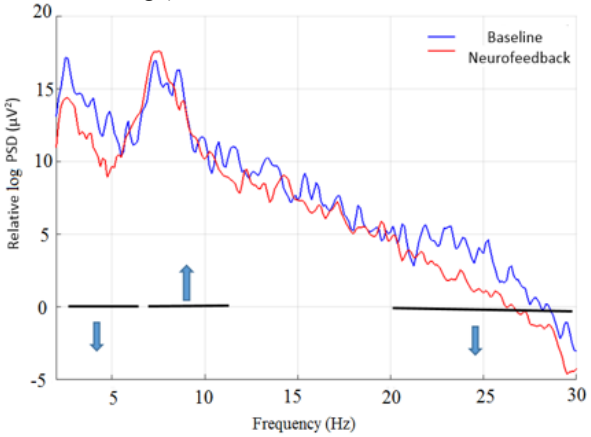

Figure 3 PSD as a function of frequency during baseline and during NF training of a representative patient during home use of BCI. Theta and higher beta band power was decreased and alpha power was increased during neurofeedback training

DISCUSSION

This feasibility study shows that lay people with a mixed social background are capable of using BCI technology on their own or with the help of their caregivers. Although there are published studies on SCI patients views of BCI technology, this is the first study in which SCI people actually used BCI on their own. Kubler et al. [12] suggested a model of user centered design with three main parameters: efficiency, effectiveness and satisfaction. In the context of this study, effectiveness could be expressed as a reduction of pain, efficiency as the number of sessions required to learn neurofeedback and time to setup the system. Although we did not use validated questionnaires for patient satisfaction as suggested in [12] we believe that custom made questionnaires (Tables 3 and 4) and semi-structured interviews cover the areas such as usefulness, expected functionality, usage pattern and patient's appearance while using a device.

Table 3: Perceived usefulness and the ease of use of a portable BCI. Question 3 contains two statements, but it was assumed that all people who attended the training were interested in having a device.

Questions	Range	Average
1.In your opinion, how easy is it to understand the main purpose of the EEG-tablet system?	1 very easy 10 very hard	2.1±0.7
2. How easy do you feel that it is to use this device on a daily basis?	1 very hard 10 very easy	8.0±1.7
3. I would like to have this device but I am not sure if my caregiver and I would understand how to use it	1 very false 10 very true	1.0±0.0
4. Please rate how much you feel convinced that the device might help reducing your pain?	1 not at all 10 very much convinced	7.9±0.7

Table 4: Attitude towards using a novel technology.

Questions	Range	Average
1. Please rate how you would feel if other people would see you wearing the device at home	1 very embarrassed 10 very amused	8.7±1.7
2. Please rate how you would feel if other people would know that you are using the device at home	1 very embarrassed 10 very amused	8.3±2.2
3. Please rate your attitude towards using a novel technology (e.g. computers, phones, other gadgets)	1 extreme avoidance 10 extreme excitement	8.4±1.0

From patients' perspective,the largest problem was to ensure that the training electrode was always close to C4 location because the headset was not designed to be used over the central area.

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Another problem was that the initial measurement of the impedance was the only check of signal quality because patients were not familiar with the morphology of EEG and could not check the raw EEG signal. A post-hoc analysis of EEG signals recorded during neurofeedback, indicated that most of the time patients were getting an EEG signal of a reasonable quality.

While we did not have a control group, from the initial set of 12 patients we selected for home based BCI study, only people who, based on our previous experience, had additional self-reported sensations (tingling, pleasant warmth) accompanying the reduction in pain. About two-thirds of patients in this study experienced a reduction of pain. Neurofeedback is a technique which requires training and some people who did not experience a reduction of pain did not learn how to control their brainwaves within 4 training sessions. We showed that people who used BCI at home achieved a larger reduction in pain with a prolonged use [5].

While for a patient, self-manged therapy is essential to have highly motivated participants, it was possible that placebo effect to some extent contributed to the reduction in pain because of patients' high expectation of the BCI. However, the main aim of this study was to test if an average adult with no previous knowledge of BCI, who may possibly need the assistance of a caregiver, could use BCI at home. We believe that this study provides some useful information for future developers of consumer EEG headsets.

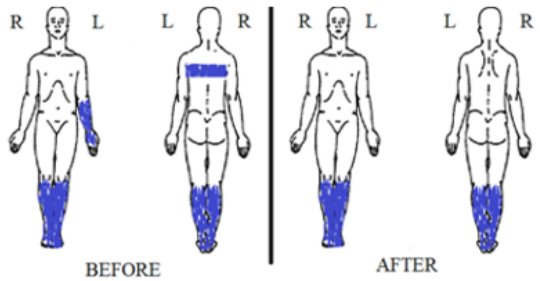

Figure 4 . Body diagram showing the location of pain in one representative patient before and after practicing neurofeedback at home for 3 months. The diagram provides an additional information to VNS.

CONCLUSIONS

The study demonstrates the feasibility of home-based patient and caregiver managed BCI therapy for CNP. The results of this study should encourage other researchers to take BCI from labs and hospitals to patients' homes and should inform the developers of wearable consumer BCI devices

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