The Use of ENAR Therapy *in Australia –*

A Phase IV Post-Market Surveillance Study

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Abstract

Objective: To report the effectiveness and safety of the ENAR device as well as the conditions for which the therapy was employed and its perceived effectiveness. The impact of therapy on medication use is also explored.

Design and setting: An Australian post-market, web-based survey of ENAR therapy users.

Results: Most respondents (76%) used ENAR exclusively for pain relief for musculoskeletal disorders, especially back, shoulder and neck pain; 8% used ENAR exclusively for non-musculoskeletal disorders; while 16% used ENAR for both. Respondents reported a mean reduction in pain of 70% [$t(423) = 38.73$, $p < .001$] and functional improvement of 62% [$t(423) = 10.45$, $p < .001$] using 11-point numerical rating scales. Following ENAR treatment medication reduction was reported by 91% of respondents. Very few respondents reported safety incidents or concerns with the therapy.

Conclusions: Most respondents reported high satisfaction and a reduction in medication use following ENAR therapy, with between 15-20% reporting complete pain relief. The self-delivery of ENAR may, in part, account for the high level of satisfaction.

Introduction

The electro neuroadaptive regulator (ENAR) device has been available on the Australian market for over 10 years. It is an approved product registered with the Australian Therapeutic Goods Administration (Listing ARTG 147761) in the product category Medical Device Class IIa along with devices such as transcutaneous electric nerve stimulators (TENS).

ENAR therapy is not well researched, however two studies have been conducted in Australia.[1,2] The first involved a randomised controlled trial on the use of ENAR therapy for chronic neck pain sufferers and showed superior efficacy for ENAR over both TENS and sham treatment alternatives. The second study was a post-market surveillance survey in which ENAR users reported their experiences on efficacy and safety of the therapy. This paper reports aspects of the second study.

While initially developed for pain relief, the ENAR device has increasingly been adopted for other purposes. These are wide-ranging with patients and therapists both reporting that the device has assisted in conditions sometimes unrelated to pain such as neurological disorders, skin disorders and so on. These reports were the stimulus to conduct the second study.

The aims of this paper are:

- to report on a survey of patients on their experiences of using the ENAR device
- to examine the range of applications to which the device is put
- to ascertain the level of efficacy for those applications by patient reports
- to review safety issues related to the use of ENAR therapy

Methods

A post-market survey model was employed where each person on the device distributor's database was contacted and asked to participate in the survey. The database contained contact details of each person who had purchased an ENAR device from the distributor or had otherwise enquired about the device. A novel 33 question survey was created seeking basic demographic information and questions surrounding the conditions for which the device was applied including the use, effectiveness and safety of the device. The protocol was reviewed by the RMIT University Human Research Ethics Committee and granted approval.

Findings

Respondent number, age, condition chronicity and gender

Total participant number was 481 of which 442 answered almost all questions. The respondents were aged between 18 and 88 years (mean 54 years, sd 14 years). The most common age among participants was 56 years. One respondent answered on his/her experiences using the ENAR on their child. Respondents generally had a chronic history of the conditions for which they used the ENAR device - chronicity averaging 6.4 years. Females comprised 69% of the respondent pool. Women are well known to be more enthusiastic consumers of health care services, including CAM services. The age and gender profile in this sample was generally consistent with the results from a 2007 Australian survey on CAM use except for our respondents being in an older age bracket.[3]

ENAR use

Respondents were asked to report the primary problem for which they used ENAR. The three most common responses (in order) were back pain, shoulder pain and neck pain. Many respondents cited more than one problem in response to this question. Musculoskeletal complaints were identified as the primary problem by 405 (91.6%) respondents, and 106 (24%) for non-musculoskeletal conditions. An overlap of 69 respondents (16%) was noted where respondents used ENAR for both. Thirty seven respondents (6%) had a non-musculoskeletal problem as their sole 'primary' complaint.

Responses were also analysed as to the pain component of the problems. Conditions with pain as their main symptom or feature were categorised as 'Painful syndromes' and those with a primary symptom other than pain were categorised as 'Non-painful syndromes'. By this analysis, 88% of respondents reported a painful syndrome as their primary problem for the use of ENAR. Table 1 lists the conditions for which ENAR was used.

Number and duration of ENAR treatments

Participants were asked about the number of ENAR treatments they had, and the typical duration of each treatment. A bipolar distribution of responses was noted with the two most likely responses describing either a short term treatment protocol (1-4 sessions) or, alternately a more lengthy regimen of therapy (20+ sessions). Making estimations for each of the responses yields a total number of treatments of about 5,500 for the cohort at an average of 25 treatments per respondent.

With respect to the duration over which therapy was rendered, most respondents (55%) reported that treatment was received over a period of months rather than days or weeks. The average reported duration of therapy across the whole sample was 172 days = 5.6 months. It is noted that a large percentage of respondents were home users who had self-administered the therapy.

Table 1: Primary problem ENAR was used for

Summary of Responses		
Region or system involved	**Count**	**%**
Low Back*	111	25
Shoulder*	60	14
Neck*	56	13
Knee*	42	10
Neurological	31	7
Ankle/Foot*	27	6
Arthritis*	25	6
Fibromyalgia*	25	6
Hip*	22	5
Headache	16	4
Wrist/Hand*	14	3
Thoracic spine*	14	3
Digestive	13	3
Other Head	12	3
Emotional	9	2
Elbow*	9	2
Skin	8	2
Hormonal	6	1
Cardiovascular	6	1
Genito-Urinary	3	1
General health	2	0
Musculoskeletal syndrome (MSK)*	336	76
Non- Musculoskeletal syndrome	37	8
Had both MSK and Non-MSK syndrome	69	16
Painful syndrome	387	88
Non-painful syndrome	55	12

Notes: A number of respondents cited more than one problem as the reason they commenced ENAR therapy. Musculoskeletal conditions are shown by *

Changes in pain level associated with ENAR therapy

A Numerical Rating Scale (NRS) was employed to record pain levels before and after treatment. Respondents were asked to select the number along the scale which corresponded to their pain level. The level of pain was asked both prior to ENAR treatment and following ENAR treatment. A change in NRS of at

least 1.3 scale points has been reported to represent a clinically significant difference which is meaningfully beneficial from the patient's perspective.[4,5] Commonly a change of at least 2.0 NRS points is a therapeutic goal.

Prior to ENAR treatment respondents had an average pain level of 7.16 NRS points. Following ENAR therapy pain levels were reported to average 2.04. This equates to a fall of 5.12 NRS points, or a greater than a 70% reduction in pain. A paired-samples t-test was used to determine statistical significance for this finding. The results show a strong and significant reduction in pain ratings, $t(423) = 38.73$, $p < .001$.

Figures 1 and 2 show NRS pain responses before and after ENAR therapy. As numbers approaching ten represent high levels of pain and numbers closer to zero represent lower levels of pain, the shift towards to left in the two graphics represents a diminution of pain responses after ENAR treatment.

Figure 1 Frequency of NRS pain level prior to ENAR therapy (Mean = 7.16)

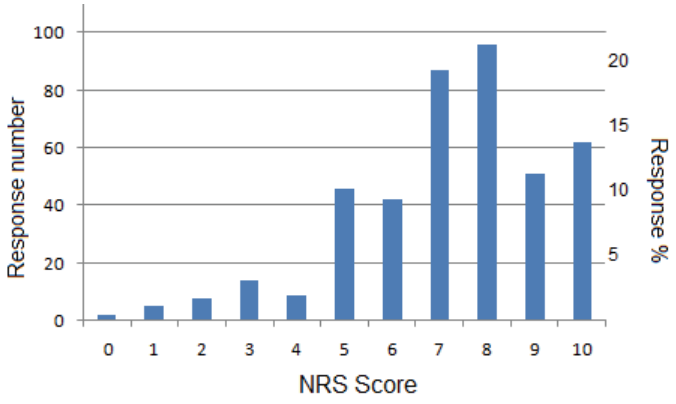
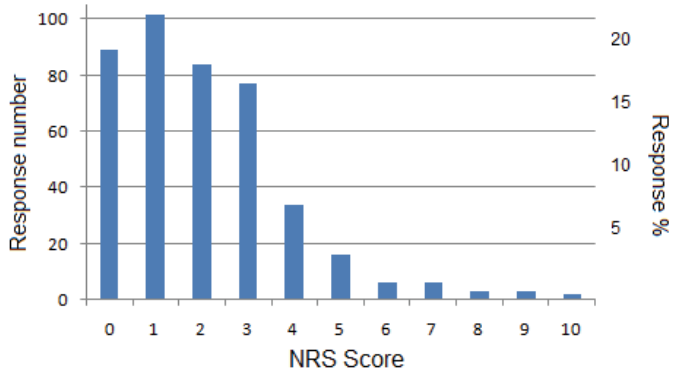


Figure 2 Frequency of NRS pain level after ENAR therapy (Mean = 2.04)



About 40% of respondents reported that the effects of ENAR treatment lasted for some days. Almost 30% found that the effects lasted for months. Surprisingly, almost 20% reported pain reduction that lasted for years, despite this being a population of chronic pain sufferers.

Changes in function or activity associated with ENAR therapy

A Numerical Rating Scale (NRS) was also employed to record level of function or activity before and after treatment. A change of at least 2.0 Functional NRS points is regarded as a clinically significant therapeutic goal. Prior to ENAR treatment respondents had an average functional activity level of 3.49 NRS points. Following ENAR therapy functional activity levels were reported to average 5.65. This equates to an increase of 2.16 NRS points, or an increase in functional capacity of 62% in their specified activity. Again, a paired-samples t-test was used to determine statistical significance for this finding. The results show a strong and significant increase in functional activity NRS, $t(423) = 10.45$, $p < .001$.

About 35% of respondents reported that the effects of ENAR treatment with respect to functional improvement lasted for some days. Almost as many (33%) found that the effects lasted for months. Once again a substantial proportion (23%) reported a treatment effect which lasted years, despite this being a population of chronic sufferers.

Relationship between length of time of primary problem (chronicity) and pain or activity changes

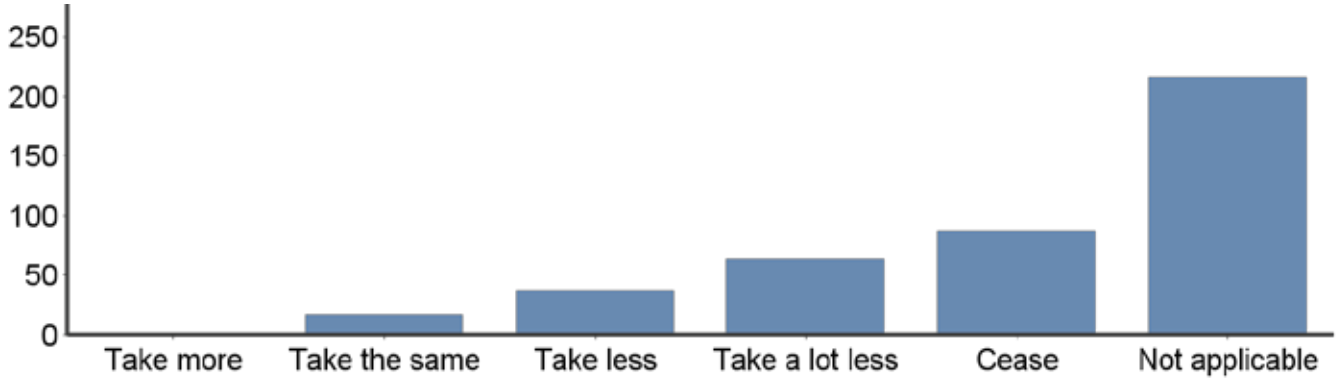
Chronicity is a major factor affecting treatment effectiveness for many types of therapy. For this reason an analysis was undertaken to ascertain whether the effectiveness of ENAR in terms of pain reduction or activity improvement was related to the chronicity of the patient's problem. A non-parametric correlation was performed. There was no significant relationship between length of time and pain reduction, $r = -.07$, $p = .08$, but there was a significant positive correlation between length of primary problem and improvement in activity, $r = .10$, $p = .009$. Participants who reported problems with higher chronicity also reported larger improvements in activity levels. This is an encouraging finding for those who have long-standing problems, which are associated with a decline in ability to carry out certain movements or functions.

Effects of ENAR therapy on medication use

The impact of ENAR therapy on use of medications was also investigated. About half of the respondents were taking medication prior to commencing ENAR therapy for their primary problem. Of these, 91% reported that because of ENAR treatment they were able to reduce or eliminate their medication use for the management of their primary problem. In this group 42% stated that they were able to cease medication altogether for their primary problem. Only one respondent of the 206 who reported that they changed their medication use following ENAR treatment said that he/she increased medication use after ENAR treatment. These results are depicted in Figure 3.

In examining the impact and value of any new or alternate therapy an important consideration is the ability for patients who use that therapy to become less reliant on other forms

Figure 3 Reported medication changes as a result of ENAR therapy



of treatment. This is especially so in terms of medication use. Any therapy which leads to reduced levels of medication is potentially attractive. In the area of pain relief, medications such as non-steroidal anti-inflammatory drugs are a common source of serious harmful side-effects. In addition, prescription drugs, which are heavily subsidised are a major drain on the National health care budget. ENAR treatment appears to offer an alternative to drug therapy in many cases, especially for painful, musculoskeletal problems.

Perceptions of end-users on the overall effectiveness of ENAR therapy

Participants were asked to rate the overall effectiveness of ENAR therapy on their primary problem. Respondents report

ENAR to be a highly successful therapy. ENAR was reported by almost all respondents (98%) to have a positive effect on their primary problem. Almost two thirds reported 'great effectiveness' and almost one in five said that ENAR 'cured' their problem.

Respondent perceptions of comparative effectiveness

Respondents were asked to rate the effectiveness of ENAR compared to other therapies that they had tried previously. On a five point scale ranging from 'Much worse' to 'Much better', 75% of respondents rated ENAR as much better. In total almost 93% rated ENAR as either 'Better' or 'Much better'. Less than 2% rated ENAR as either 'Worse' or 'Much worse' than alternative therapies they had tried.

Adverse effects in using ENAR

All therapies which are effective carry with them a degree of harm or adverse outcome. A therapy is desirable if its efficacy profile is at least as good as alternative therapies and if its adverse effects are minimal or at least acceptable in the context of clinical decision-making.

Seven percent of respondents (30) reported a negative or adverse event. Respondents were asked to specify details of their response. On review of individual response descriptions most are relatively trivial and related episodes of subsequent short-term discomfort. Mild electric shock was noted, as was aggravation of the condition if the therapy was excessively applied. It is recommended that practitioners and home users be advised that excessive use of the ENAR device may cause a mild adverse event. Further, that under such circumstances one could expect to experience short-term muscle soreness, nausea, headache or tiredness. Considering the high levels of effectiveness reported by participants, the low frequency of reported adverse effect, and the minor nature of those effects, ENAR can be regarded as a safe treatment.

Limitations to this study

As this was a retrospective study, recall bias is an inherent weakness. Another limitation is regression to the mean. The natural history of most health care complaints is that they tend to get better over time and individuals who try a therapy are most likely to do so when their condition is at its worse. As the severity of most conditions fluctuates over time, it is to be expected that people undergoing treatment are likely to improve over time. For this reason, the results of the comparisons between therapies in this report are probably more valid than the results reported for the therapy itself. As both accounts were favourable towards ENAR, this difference may be moot. This study did not have a placebo control group. Because of this it is not possible to measure the magnitude of efficacy of ENAR therapy. Therefore, the conclusions presented here are conservative.

Conclusions

Post-market survey respondents reported high levels of effectiveness of ENAR and low frequency of adverse effects which were of minor nature. The main conditions for which ENAR is used are painful musculoskeletal complaints, although a wide range of other types of problems were reported to have been successfully managed with ENAR. Most respondents reported that they had decreased their use of medication following ENAR therapy. Further prospective, controlled trials should be conducted to better understand the potential of ENAR as an emerging therapy.

A feature of ENAR is its facility to be self-used, not practitioner dependent. In terms of health care sociology, this is in keeping with attitudes which embrace higher levels of personal control or empowerment over one's health. This may have contributed to the high level of satisfaction with ENAR.

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Competing Interest

None.

References

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