

## Home based application of transdermal cryoanalgesia as interventional pain management among Nigerian physiotherapists

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**Abstract.** *Aim and scope:* The primary purpose of this study was to sample the opinion of physiotherapists on the prescription of cryoanalgesia for patients' home based use in Nigeria. *Material and methods:* A total of 152 physiotherapists (PTs) were selected from hospitals in south-west Nigeria. The instrument used in this study was a structured self-administered questionnaire. The respondents were to choose option of either 'Agree' or 'Disagree' with each opinion statement in the questionnaire. *Results:* One hundred and seven (70.4%) were practising prescription of cryoanalgesia because they felt their clients needed more treatment sessions than they offered at the clinic. However, their prescription was not due to exhaustion at work during normal clinic hours. The PTs who believed that the treatment sessions at the clinics were inadequate was significantly higher ( $X^2 = 262.5$ ,  $p < 0.05$ ) than those who felt it was appropriate. Among those that were yet to practise the prescription for home-based use, 100 (65.8%) indicated their readiness to do so if they feel their clients need more treatment sessions than they have offered at the clinic. Furthermore, most physiotherapists significantly disagreed with the opinion that they have preference for other modalities to manage pain ( $X^2 = 74.907$ ,  $P = 0.001$ ), or that there were inadequate scientific evidences supporting the usage of cryoanalgesics ( $X^2 = 99.227$ ,  $P = 0.001$ ). The result showed that most physiotherapists significantly agreed that the possibility of contraindications ( $X^2 = 72.257$ ,  $P = 0.001$ ) and the possibility of complications ( $X^2 = 4.252$ ,  $P = 0.001$ ) might prevent them from prescribing cryoanalgesia.

**Key words:** *rehabilitation, transdermal cryoanalgesia, pain, physiotherapy*

### Introduction

Home based rehabilitation (HBR) or Home Based Physiotherapy (HBPT) is a programme made available to patients who need continuous physiotherapy treatment at the comfort of their homes (1). Maximizing functional independence of patients has been put as one of the potential benefits of Home Based practice (2). Similarly, cost effectiveness and reduced burden on in-patient hospital bed space has been observed to be another potential benefit of the practise [3]. Cryoneuroablation, also known as cryoanalgesia or cryoneurolysis, is a non-pharmacological technique that provides long-term pain relief in interventional pain management settings (4, 5). Cooper et al (6) developed a device that used liquid nitrogen in a hollow tube that was insulated at the tip and achieved a temperature of - 190 degrees Centigrade. Lloyd et al (7) proposed that cryoanalgesia was superior to other methods of

peripheral nerve destruction, including alcohol neurolysis, phenol neurolysis, or surgical lesions. Transdermal cryoanalgesia is the local or general application of cold for therapeutic and preventive uses, and essentially to relieve pain. Other therapeutic use include relief of muscle spasm, reduction of swelling, facilitation of muscle contraction, increasing muscle endurance, reduction of haematoma formations, prevention of pressure sores and promotion of wound healing (8). It has also been documented to increase pain threshold (9).

It can be applied in the forms of damp towels dipped in ice-and-water mixture, or damp towels containing crushed or flaked ice, or as pack, or by immersion in a bath containing ice-and-water mixture, or in the form of an ice massage which can be an ice cube or ice lolly wrapped in a towel at one end and the other end of the ice exposed.

The application is associated with reduction in nerve conduction associated with spontaneous drop in temperature or the counter-irritant sensory effect of the ice application on the skin (8). Intense cooling of peripheral nerves to temperatures below  $-5$  to  $-20^{\circ}\text{C}$  causes disintegration of axons and breakdown of myelin sheaths without disrupting the perineurium and epineurium and the subsequent effect is an interruption of nerve conduction (and pain relief) for several weeks (10). An invention – cryo Hit (R) by Gallil medical delivers localized cryoanalgesia through a probe that is placed in contact with tissues, which contain sensory nerve fibres near a surgical incision. The probe cools the nerve tissues to minus  $70^{\circ}\text{C}$  over the course of the 30 seconds treatment per site. Cryo Hit is an advanced drug free pain relief in 30 seconds (11). There has been a consensus on the application of ice (or cold) for 20–30 minutes results to decrease pain, blood flow and metabolism, although this evidence is not fully certain, (13-15). The duration of ice application should be reduced over superficial nerve trunks, or in patients with little subcutaneous fat (15, 16), but increased in individuals with large subcutaneous deposits of fat (17).

The most effective mode of application of cold seems to be chipped ice in a damp towel (18). The Association of Chartered Physiotherapists in Sports Medicine (19) reported in clinical guidelines for sport injuries that crushed ice was the most common mode of application of cold in the hospital/ clinic setting with a frequency of three to five times per day. However, there have been reports of burns as a result of continuous cryotherapy application for periods more than 40 minutes especially when skin sensation is impaired. Undocumented reports have observed that patients suffer ice burns and nerve injuries secondary to overdose or wrong application of cryotherapy (19). In the clinical setting, cryotherapy is most often performed by a physical therapist or a Physical Therapist assistant. However, with proper instruction from a physical therapist (PT) or a PT assistant, cold pack and ice massage treatments can be performed by the patient or with the help of a caregiver at home (20). Exercise therapy is also frequently prescribed for patients in home programmes; most patients may experience tissue reaction and increased pain intensity after the exercise for which cryotherapy has reportedly indicated for effective alleviation (21). This is in addition to the

use of cryotherapy usually in acute and in some chronic soft injuries.

Most Nigerian physiotherapists are involved in Home Based Rehabilitation (HBR) (3). They are involved in practice of prescribing Cryoanalgesia and exercise therapy un-mindful of the hazard usually associated with wrong application and dosage for clients use at homes. Considering cases such as skin insensitivity, chest injuries, angina pain and high blood pressure, there is the need for precautionary measures and education before applying cryotherapy (22). Applying cold to someone with high blood pressure will result in vasoconstriction which will further increase the pressure within the vessels (22). The different categories of pain affects the quality of life of patients and it poses challenges to professionals who are involved in the management of pain. Physiotherapists are faced with the greatest challenges of managing both acute and chronic pain because they are tasked with the end point of medical rehabilitation, hence, for effective management there may be need for continuing treatments at homes. There is inadequacy of data regarding the prescription of cryoanalgesia for patients' home based use by physiotherapists in Nigeria.

### **Material and Method**

*Sample and Sampling Technique.* A purposive sampling method was applied to recruit physiotherapists based on the inclusion criteria that they are practising and are registered with the Nigerian Medical Rehabilitation Therapists Registration Board, Nigeria. All respondents voluntarily agreed to participate in the study. A total of 152 physiotherapists were selected from hospitals and institutions in south-west Nigeria.

*Research Design.* A cross-sectional quantitative survey design was used. In this survey, the respondent completed the questionnaire when it was convenient and could check personal records if necessary. This survey offers anonymity and avoids interviewer bias. In addition, it is very effective, and response rates may be high for a target population that is well educated or has a strong interest in the topic or the survey organization (23).

*Instruments.* The instrument used in this study was a structured self-administered questionnaire which comprised of closed-ended questions only. Section A was designed to obtain demographic details, training and knowledge background of the physiotherapists. Section B of the questionnaire

was designed to obtain the practice characteristics and opinion of the physiotherapists concerning the prescription of cryoanalgesia. The respondents were to choose option of either 'Agree' or 'Disagree' with each opinion statement in the questionnaire.

The study was pre-tested on a sample of convenience in order to improve the clarity of the questions and instructions, comprehension, format and readability to ensure the face and content validity of the questionnaire. The questionnaires were distributed to 10 physiotherapists in the departments of physiotherapy of the Obafemi Awolowo University and Obafemi Awolowo University Teaching Hospitals. All adjustments were made based on the feedback received to ensure the validity and reliability of the questionnaire. Changes to the survey instrument were made based on their feedback. Previous literature related to physiotherapists knowledge, attitudes, perception; and use of electrotherapy or electro-physical agents; and prescribing rights of the physiotherapists was used to support the content validity of the instrument (24).

**Procedure for Data Collection.** Ethical approval was sought from the Ethics and Research Committee of Obafemi Awolowo University Teaching Hospital complex, Ile-Ife, Osun State, Nigeria. The test instrument was distributed by hand. A letter was submitted to the heads of department introducing the investigator and also to seek permission to conduct the study in their institutions. Information about the population of clinicians in the participating hospitals was obtained from the respective heads of physio -

therapy departments, to determine the number of questionnaires to distribute in each hospital. Verbal consents were obtained from the participants and the aims of the study were explained. Participants were also assured of the confidentiality of information given and they were informed that their participation was voluntary and that they had the right to withdraw from the study.

**Data analysis.** Data collected from this study were analyzed using descriptive statistics of frequency, and percentages. Inferential statistics using the Chi-square was used to compare the mean percentage difference in the number of respondents listed. Data analysis was done using the statistical package for social sciences software, version 17.

### Results

A total of 200 copies of the questionnaires were distributed, 152 copies were returned and were valid for analysis. This revealed a response rate of 76%. Demographic details, respondents work settings and history of knowledge update was presented in table I and II. 107 subjects (70.4%) were already practising prescription of cryoanalgesia; they felt their clients needed more treatment sessions than they were being offered at the clinic. This showed that PTs who believed that the treatment sessions at the clinics were inadequate was significantly higher ( $X^2=262.5$ ,  $p<0.05$ ) than those who felt it was appropriate. Only 3(2.0%) respondents indicated that they usually prescribe because they get exhausted at work during their clinic – based treatment (table II).

**Table 1.** Respondents demographic profile

Variable	Frequency	Percentage
<b>Gender</b>		
Male	84	55.3
Female	63	41.4
<b>Age Range</b>		
20 – 24	12	7.9
25 – 29	41	27.0
30 – 39	67	44.1
40 – 49	28	18.4
50 – 59	4	2.6
60 – 69	-	-
70 and above	-	-
<b>Years of Experience</b>		
Less than 1year	22	14.5
1 year	6	3.9
2 – 5 years	38	25.0
6 – 10 years	31	20.4
11 – 20 years	42	27.6
Above 20 years	11	7.2
<b>Highest Physiotherapy Degree</b>		
Bachelor Degree	109	71.7
Master Degree	42	27.6
PhD Degree	1	0.7

**Table II.** Respondents work settings and history of knowledge update

Variable	Frequency	Percentage
<b>Work Place</b>		
Teaching Hospital	86	56.6
Private Hospital	2	1.3
State Hospital	20	13.2
Others	44	28.9
<b>Knowledge Update History</b>		
Never	6	3.9
Over 10 years ago	9	5.9
6 – 10 years ago	12	7.9
1 – 5 years ago	38	25.0
Less than 1 year	25	16.4
Recently	61	40.1
<b>Knowledge Update Source</b>		
Via another physiotherapist	16	10.5
Journal	33	21.7
General medical practitioner	1	0.7
Via the physiotherapy registration board	1	0.7
Training schools (e.g. university)	18	11.8
Manufacturers' advertising campaign	6	3.9
Others	13	8.6
Multiple sources	56	36.8

When asked if respondents will be willing to prescribe because of any of the stated reasons especially for those who were yet to practise prescription of cryoanalgesic modalities for home-based (self-administered) use by patients, 100

(65.8%) indicated their readiness to do so if they feel their clients need more treatment sessions than they have offered at the clinic while 30 (19.7%) respondents indicated that they would not prescribe because of the stated reason (Table III).

**Table III.** Respondents' reasons for prescribing cryoanalgesic modalities

Variables	Yes		No	
	N	%	N	%
<b>Those who practised the prescription</b>				
Inadequate treatment sessions at the clinic	107	70.4	27	17.8
Exhaustion at work during clinic – based treatment	3	2.0	123	80.9
<b>Those who indicated their willingness to prescribe</b>				
Inadequate treatment sessions at the clinic	100	65.8	30	19.7
Exhaustion at work during clinic – based treatment	9	5.9	113	74.3

When asked concerning the modalities usually included in their treatment programme for pain. One hundred and thirty seven respondents (90.1%) and 151 (99.3%) respondents indicated they included exercises and cryoanalgesics (ice) respectively in their clinic-based treatment programme for pain. On home based-based programmes, 134 (88.2%) included exercises in their clients' home-based (self-administered) treatment while 132 (86.8%) prescribed cryoanalgesics programmes for pain management (Table 4).

When asked if exercise and cryoanalgesia being prescribed for Home Based use have dosages, 142 (93.4%) respondents indicated yes while 5 (3.3%) stated otherwise (Table IV). When further asked to indicate their willingness to prescribe exercise and cryoanalgesia for home-based (self-administered) use if it was indicated in their clinic based treatment, 139 (91.4%) respondents representing the majority indicated their willingness to prescribe them. Nine (5.9%) respondents indicated their non-willingness to prescribe the modalities.

**Table IV.** Modalities usually included in treatment programme for pain

Modalities	Clinic-based				Home-based			
	Yes		No		Yes		No	
	N	%	N	%	N	%	N	%
<b>Exercise</b>	137	90.1	13	8.6	134	88.2	17	11.2
<b>Cryoanalgesia</b>	151	99.3	1	0.7	132	86.8	19	12.5
<b>Dosages</b>	142	93.4	5	3.3	139	91.4	9	5.9

The result of the study revealed that 144 (94.7%) of the respondents thought their prescribed home-based (self-administered) treatment programmes have been effective for their clients. One hundred and forty respondents (92.1%) indicated that they assess their patients' level of adherence to their home-based (self-administered) physiotherapy treatment for pain.

However, only eighty-two (53.9%) respondents stated that they were satisfied with their patients' level of adherence to the home-based (self-administered) physiotherapy treatment for pain, while 64 (42.1%) respondents stated that they were not satisfied with the level of adherence (Table V).

**Table V.** Respondents' opinion on effectiveness and assessment of patient's level of adherence

	YES		NO	
	N	%	N	%
Effectiveness of home-based treatment	144	94.7	6	3.9
Patients' level of adherence to home-based treatment	140	92.1	9	5.9
Satisfaction with patients' level of adherence	82	53.9	64	42.1

One hundred and twenty-eight (84.2%) respondents indicated that there was no legislation against the prescription cryoanalgesia and exercise therapy by other allied health professionals in regions where they practice. However, one hundred and twenty four (81.6%) indicated that they would support an enactment or a revision of an act that will permit the prescription of the home-based cryoanalgesic by physiotherapists only. The result further showed that 96 (63.2%) indicated that they were ready to support an enactment or a revision of an act that will permit the prescription of the home-based cryoanalgesic by other allied health professionals (Table 6). The Chi-square test showed that most physiotherapists significantly disagreed

( $X^2 = 96.960$ ,  $P = 0.001$ ) with the opinion that they were not legislated to prescribe cryoanalgesics, hence, they will prescribe cryoanalgesics. Likewise, most physiotherapists significantly disagreed with the opinion that they were not qualified to prescribe cryoanalgesic ( $X^2 = 267.232$ ,  $P = 0.001$ ); that supervision was required for the administration of the cryoanalgesics ( $X^2 = 22.427$ ,  $P = 0.001$ ), hence, they will prescribe cryoanalgesics. Furthermore, most physiotherapists significantly disagreed with the opinion that they have preference for other modalities ( $X^2 = 74.907$ ,  $P = 0.001$ ), or that there were inadequate scientific evidences supporting the usage of cryoanalgesics ( $X^2 = 99.227$ ,  $P = 0.001$ ) (Table VII, VIII and IX).

**Table VI.** Knowledge and support concerning legislation on prescription of cryoanalgesia and exercise therapy

	Yes		No	
	N	%	N	%
Prescription by other allied health professionals	23	15.1	128	84.2
Prescription by non-health professionals	41	27.0	110	72.4
Enactment of an act that will permit physiotherapists only	124	81.6	23	15.1
Enactment an act that will permit other allied health professionals	48	31.6	96	63.2

The result also showed that most physiotherapists significantly agreed that the possibility of contraindications ( $X^2 = 72.257$ ,  $P = 0.001$ ) and the possibility of complications ( $X^2 = 4.252$ ,  $P = 0.001$ ) that might be associated with the prescription of cryoanalgesics will prevent them from prescribing it (Table 7, 8 and 9). However, there were no statistically significant differences in number of physiotherapists who agreed and disagreed concerning not prescribing cryoanalgesic modalities for home-based (self-administered) use by patient for reasons such as the possibility of the patient's non-adherence with the prescribed

cryoanalgesic treatment ( $X^2=2.021$ ,  $p=0.16$ ) and concerning risks associated with the unsupervised use of cryoanalgesics ( $X^2=3.315$ ,  $p=0.07$ ). Likewise, the Chi-square test also revealed that there were no statistically significant differences in the number of physiotherapists who agreed and disagreed concerning not prescribing cryoanalgesic modalities for home-based use due to the risk of burn ( $X^2=3.550$ ,  $p= 0.06$ ); and lastly because it would encourage the practices of unprofessional acts ( $X^2 =2.667$ ,  $p=0.10$ ) (Table VII-IX). One hundred and forty-four (94.7%), 100 (65.8%), and 95 (62.5%) respondents

reported that cryoanalgesics could be prescribed for acute pain, sub-acute pain, and back pain respectively.

Ninety-six (63.2%), 103 (67.8%) respondents also chose to prescribe cryoanalgesics for musculoskeletal and neuropathic pain respectively (Table X).

**Table VII.** Respondents opinion on non-prescription of cryoanalgesics for home-based (self-administered) use

Variables	AGREE		DISAGREE		X <sup>2</sup>	P
	N	%	N	%		
Not legislated to prescribe	15	9.9	136	89.5	96.960	0.001
Not qualified to prescribe	5	3.3	145	95.4	267.232	0.001
Supervision required	46	30.3	104	68.4	22.427	0.001
Inadequate knowledge	11	7.2	136	89.5	106.293	0.001
Inadequate knowledge about the dosage	7	4.6	142	97.4	121.324	0.001
Non-adherence to prescription	63	41.4	80	52.6	2.021	0.155
Possible contraindications	79	52.0	68	44.7	72.257	0.001
Possible complications	86	56.6	61	40.1	4.252	0.039
Risks associated with non-supervision	84	55.3	62	40.8	3.315	0.069

**Table VIII.** Participants opinion on non-prescription of cryoanalgesics for home-based (self-administered) use

	AGREE		DISAGREE		X <sup>2</sup>	P
	N	%	N	%		
Expensiveness	17	11.2	133	87.5	89.707	0.001
Unavailability	15	9.9	134	88.2	95.040	0.001
Not indicated	40	26.3	109	71.7	31.953	0.001
Difficult to operate	19	12.5	132	86.8	84.563	0.001
Patient's consent to prescribe required	41	27.0	108	71.1	30.128	0.001
Inadequate evidence	14	9.2	136	89.5	99.227	0.001
Possible overdosing	95	62.5	54	35.5	11.282	0.001
Inadequate knowledge	8	5.3	142	93.4	119.707	0.000

**Table IX.** Opinion on non-prescription of cryoanalgesics for home-based (self-administered) use

	AGREE		DISAGREE		X <sup>2</sup>	P
	N	%	N	%		
Ineffectiveness of the modality	17	11.2	132	86.8	88.758	0.001
Efficacy of other modalities	33	21.7	115	75.7	45.432	0.001
Non-adherence to clinic attendance	60	39.5	88	57.9	5.297	0.020
Risk of electric shock/burn	86	56.6	63	41.4	3.550	0.060
Religious beliefs	9	5.9	141	92.8	116.16	0.001
Patient's bias	20	13.2	126	82.9	76.96	0.001
Encourage unprofessional act	65	42.8	85	55.9	2.67	0.102
Preference for other modalities	22	14.5	128	84.2	74.91	0.001

**Table X.** Conditions for which respondents would prescribe cryoanalgesic modalities

	YES		NO	
	N	%	N	%
Acute pain	144	94.7	5	3.3
Sub-acute pain	100	65.8	48	31.6
Chronic pain	33	21.7	112	73.7
Back pain	95	62.5	53	34.9
Other MP	96	63.2	52	34.2
Phantom pain	20	13.2	127	83.6
Neuropathic pain	103	67.8	44	28.9
None	7	4.6	143	94.1

## Discussion

The transdermal application of cold to tissues creates a conduction block and physiological effect is same as of local anesthesia. Long-term pain relief from nerve freezing occurs because ice crystals create vascular damage to the vasonervorum, which produces severe endoneural edema. Cryoanalgesia disrupts the nerve structure and creates wallerian degeneration, but leaves the myelin sheath and endoneurium intact (5). Persistent chronic pain unresponsive to pharmacologic therapy substantially impedes a normal lifestyle, and must be treated aggressively (25). Pharmacologic therapy is easily prescribed, typically well tolerated, yet mostly ineffective for the treatment of chronic neuropathic pain (26).

The aim of this study was to determine the Opinion of Nigerian physiotherapist concerning the prescription of cryoanalgesia for patients' home based (self-administered) use. This study showed that majority of the Nigerian physiotherapists prescribe home-based (self-administered) treatment programme for clients. The result of this study revealed that majority of the Nigerian physiotherapists prescribe cryoanalgesic modalities because they feel their clients need more treatment sessions than they were offered at the clinic but exhaustion at work was not the reason for prescribing it.

For home-based treatment programme for pain, majority of the Nigerian Physiotherapists indicated that they included exercises and cryoanalgesia in their clinic-based treatment programmes for pain and they are aware and conscious of it that exercises, and cryotherapy commonly used in the treatment of painful conditions are dosage specific for home based prescription. Majority of Nigerian physiotherapists also indicated that they assess the patients' level of adherence to home-based (self-administered) physiotherapy treatment for pain while a moderate number of PTs reported that they were satisfied with their patients' level of adherence to their home-based (self-administered) physiotherapy treatment for pain. Furthermore, the results of this study showed that most Nigerian Physiotherapists believed that the prescribed home-based (self-administered) treatment programmes have been effective for clients. Most patients can not tolerate pain intensity at homes; hence, they will be willing to seek for means to modulate pains.

Several factors (such as legislation, qualification, knowledge about operation and dosage of modality, expensiveness of modality,

unavailability of modality) will not deter, prevent or invalidate the prescription of cryoanalgesic modalities for home based use. Similarly, other factors such as patient's difficulty to operate modality, consent, religious beliefs, bias, and non-adherence to clinic attendance as well as encouragement of unprofessional act and preference for other modalities will also not deter, prevent or invalidate the prescription of cryoanalgesic modalities for home based use. For these factors, the study showed that Nigerian physiotherapists will not be prevented from prescribing cryoanalgesia for home-based use and this could only be attributed to the importance associated with constant and consistent means to alleviate pain experienced by patient outside normal clinic hours.

Most respondents significantly disagreed that they were not qualified to prescribe the modality and that they have inadequate knowledge about the application, dosage and that preference for other modalities would deter them from prescribing cryoanalgesia. However, there were no statistically significant differences in the number of physiotherapists who agreed or disagreed concerning not prescribing cryoanalgesic modalities for home-based (self-administered) use by patient for reasons such as the possibility of the patient's non-adherence with the prescribed cryoanalgesic treatment; risks associated with the unsupervised use of cryoanalgesics; the risk of burn; and that it would encourage the practices of un-professionalism. There is still controversy over how long to apply ice. Current research suggests that during the first 24-48 hours after injury ice should be applied for 10 minutes and repeated every 2 hours (22). Application of ice pack for more than 10 minutes will cause a reflex reaction (Hunting effect) where the blood vessels dilate and blood is again pumped into the injured area, causing further bleeding and swelling (22).

This study revealed that some factors such as necessity of supervision, contraindications, complications, non-adherence to prescription, risks associated with non-supervision, possible overdosing, and risk of burns, and practise of un-professionalism were influential in their decision to prescribe cryoanalgesia. However, the study revealed that cryoanalgesic modalities were widely prescribed in various range of painful conditions during acute, sub-acute and chronic phases; back pain, musculoskeletal dysfunction, phantom and neuropathic pain.

Several studies have established the relevance of cryotherapy in the management of musculoskeletal and neuropathic pain (11, 25). Cryoanalgesia has been used with variable success as a neuroablative method for the treatment of chronic hip adductor spasticity, post-thoracotomy pain, and peripheral neuropathy (27-31). Cryotherapy depending on the forms used as well as the nature of the painful condition has been used for varying treatment parameters in terms of application time ranging from 5 minutes to 40 minutes (19) and recommended frequency of application varying between 20 minutes in every hour to 30 minutes every two hours (14).

This study concluded that most Nigerian physiotherapists prescribe cryoanalgesic modalities for clients' home-based use with the belief that the patients need more treatment sessions than they were being offered at the clinics. However, their prescription was not due to exhaustion at work during normal clinic hours. They opined that contraindications, complications, non-adherence to prescription, risks associated with non-supervision, possible overdosing, and risk of electric shock/burn were among reasons that could prevent them from prescribing cryoanalgesia for home based use.

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