

Case Report: Management of Pain After Cryolipolysis

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ABSTRACT

Cryolipolysis is a noninvasive, non-surgical clinically proven procedure to completely eliminate unwanted adipose tissue using cold. The specific sensitivity of white adipose cells to cold injury made this revolutionary technique get the US FDA clearance for fat reduction in September 2010. Since then, different body areas have been cleared to be treated. Common minor side effects include mild discomfort, bruising, edema, erythema, skin sensory alterations including numbness, tenderness and hardness in the treated areas. Some patients may refer different intensity of pain that could affect normal daily activities. The appearance of pain is reported to be less than 0,04 per application. Due to its individual and personal characteristic we have to be aware of pain and be ready to properly offer guidance regarding diagnosis, treatment and follow-up.

Keywords: Cryolipolysis; Pain

Introduction

Results from studies exploring the cold effect cold on tissue destruction have suggested that temperatures reaching 1°C can decrease the viability of adipocytes [1]. Coolsculpting® is a noninvasive procedure that uses cold to reduce unwanted subcutaneous fatty collections: cryolipolysis. The FDA gave clearance for fat reduction in different areas such a abdomen, flanks, inner and outer thighs, sub mental area, arms, back, bra fat, and area beneath the buttocks. The procedure implies the usage of a vacuum applicator (except in treatment involving the outer thigh) properly set on the skin surface of the area targeted. The period of time for each treatment that varies from 35 to 75 minutes [2]. During this period of time CoolSculpting® system extracts the heat from the skin by lowering its temperature

to around -11°C, -13°C [3]. This decrease in skin temperature makes the subcutaneous fat temperature decrease to 4°C, inducing theoretically, apoptosis only in adipocytes [4]. A manual massage follows the procedure. This massage lasts for over 2 minutes, and it has to be intense in order to get the maximum benefit. Previously to the applicator step, a specific protocol of anthropometric study and taking pictures has to be carried out and the same photographs are taken in the follow up visits at 8, 16 and 24 weeks. CoolSculpting® offers a non-surgical viable option with short recovery time, sparing adjacent structures (skin, muscle, vessels and nerves) to be affected and few minor and transient sides' effect. Pain, is an undesirable complain that may occur, and even though its relatively well tolerated by patients and not the most frequent side effect [5] it can harvest doubts in relation with the final outcome or the treatment.

Pain

The technology involving CoolSculpting® involves selective adipocytes apoptosis, and therefore an inflammatory process, [6] which show its peak at about 2-3 weeks, and slowly decreases for over 12-14 weeks depending on the applicator used for the treated area. Within 4 months the final result can be witnessed, and side effects are largely resolved [7]. We can find in the area treated macrophages, mast cells, neutrophils and granulocytes all of them inflammatory mediators causing positive symptoms secondary to tissue damage. Having in mind that this protective pain is one of the main features of inflammation and acknowledging. This inflammation is the desired effect with CoolSculpting® and somehow has to be preserved, pain can't be miss evaluated and we can't afford to have the patients dealing with it on their own. This adaptive pain has to be treated as long as possible just with painkillers, as the main goal is to reduce it while preserving the inflammatory process. The use of anti-inflammatory drugs may diminish the final outcome of the percentage in fat reduction. The fact that the apoptotic process is well known allows the physician to concentrate on dealing just with the pain sensation.

The pain may limit movement and discourage physical contact. In some way it protects the area, as the patient tends to rest and reduce further risks. However, given its subjective sensation, some patients may refer as unbearable while others may deal with it with no discomfort whatsoever. With CoolSculpting®, prevention and control of pain are essential; and optimal management requires an understanding of its physiology as well as its relationship with the desired apoptosis. Anticipating pain control by administrating oral or parenteral medication to optimize analgesia improves patient satisfaction [8] and reduces side effects such anxiety or insomnia.

It has been described that in absence of the noxious stimuli (low temperature, suction or the 2 minutes massage), the peripheral terminals may become sensitized during inflammation and axons could become sufficiently hyper excitable to generate spontaneous action potentials leading to a decrease in the threshold for generating pain and at the same time an increase in pain duration, amplitude and spatial distribution [9].

Case Presentation

A Forty-five years old woman with desire of been evaluated from her flanks and abdomen to undergo Coolsculpting treatment presented to our clinic. She had a history of dorso lumbar left lateral scoliosis without any pathologic cause determined, diagnosed at adolescent age. It evolved asymptomatic and since the risk of progression was very low, she was treated by conservative means with bracing and back muscle strength exercise prescription.

The neurologic and physical examination was normal with exception of the curvature of the spine. She was evaluated to reduce subcutaneous fat from the flanks and her weight at that time was 55.5 Kg (BMI: 21.9). Due to her spinal deviation in the left flank the surface of the Cool Smooth Pro Applicator (normally used to treat the outer thigh fat), properly fit the target area while in the right flank it was needed to apply twice the Cool Advantage Curve Plus applicator. Following the skin marking, and baseline photography protocol, the treatment began with the right flank and the 2 Cool Advantage Curve Plus applications were performed. The time involving this first treatment was approximately 165 minutes. Post clinical assessment revealed no bruising and she pointed 2 for pain in the Numeric Pain Rating Scale (NPRS). (Figure 1) The treatment of the right flank began right away, and it was completed. After the skin massage she referred pain of 2 points (NPRS).

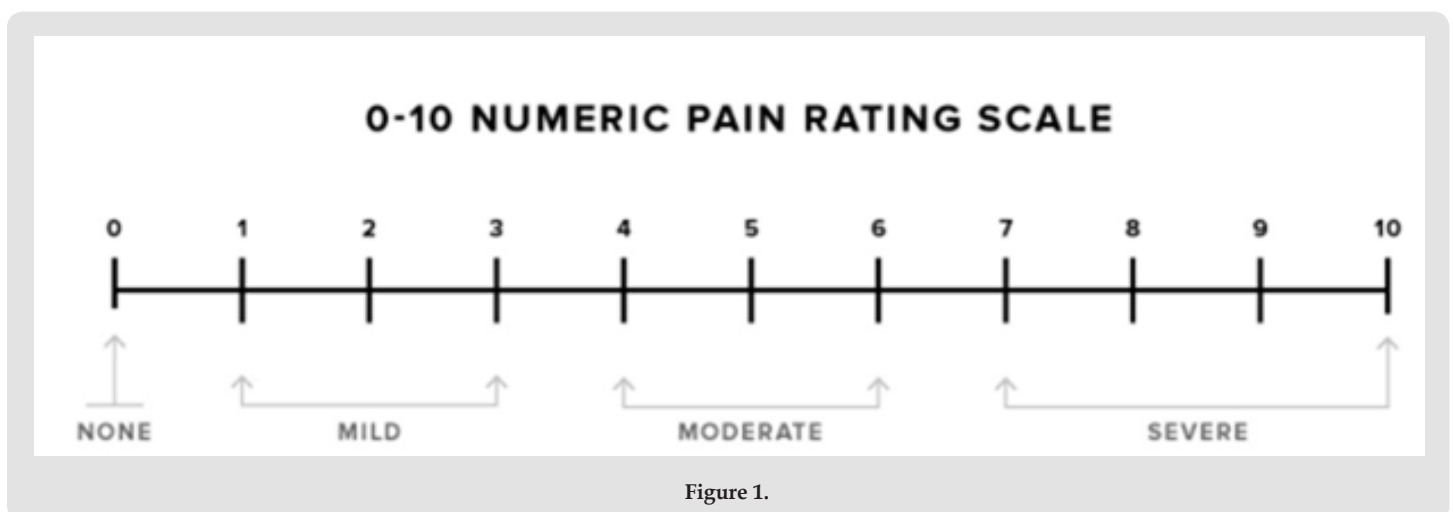


Figure 1.

We then proceeded to treat the left flank but unfortunately the patient fell asleep, making the Smooth Pro slide slightly but enough as to loosen contact with the skin. The treatment was almost over but she still had 8 more minutes to finish it. The CoolSculpting technology stops the machine automatically if a thermal event or the contact between the cup and the skin is lost. In this case due to the former, the cycle stopped without ending the treatment. It was explained to her that as the treatment wasn't completed, we were forced to repeat it all over again in that flank. Unfortunately, it was too late for her so we decided to arrange a new appointment in 72 hrs. She was discharged the same day and we perform follow up at 24, 48 and 72 hrs. In the right flank NPRS stayed at 2-3 NPRS and little erythema took place. The right flank didn't show any sign or symptom whatsoever. This support the fact that due to the failure of the treatment properly finished (8 minutes left) the skin probably never reached the adequate temperature and therefore the inflammation and apoptosis cascade were not generated. We then proceeded to treat the left flank as planned and this time the cycle successfully was completed. When applying the skin massage she pointed 4-5 in the NPRS, showing us an increase in the pain sensation after using Smooth Pro.

Forty-eight hours follow up was performed and when asking the patient for any kind of symptom such as pain, numbness or erythema,

she didn't referred any of them in the right flank, however in the left flank she started feeling little discomfort when wearing jeans, but no other symptoms. That night the sensation in the left flank began to change. She had an uneasy sleep and when she woke up the area was erythematous, and the sensation was accompanied by numbness, paresthesia, persistent pain, tingling (5-6 in the NPRS) and dysesthesia referred as hyperesthesia. The discomfort changed from little to mild. It was very significant as she couldn't bear the contact with her jeans (burning sensation) and had to wear a light dress instead. During the next 2 days the pain increased to 7 in the NPRS, and she could barely sleep, showing signs of insomnia and anxiety. The pain at night reached 8 in the NPRS scale and was quoted as severe. She was instructed to take some pain killers and hypnotic medication to be able to sleep and bring down the anxiety. This uncomfortable sensation brought about some doubts regarding the final result, and she started wondering for how long the pain would last. Concerns about the final outcome of the treatment was also verbalized. No bruising or edema appeared and the symptoms started wearing off following three days after the oral treatment was prescribed. The symptoms finally disappear 10 days after the CoolSculpting treatment. Pain sensation though uncomfortable didn't affected the final outcome of the CoolSculpting as shown in the (Figure 2) below.

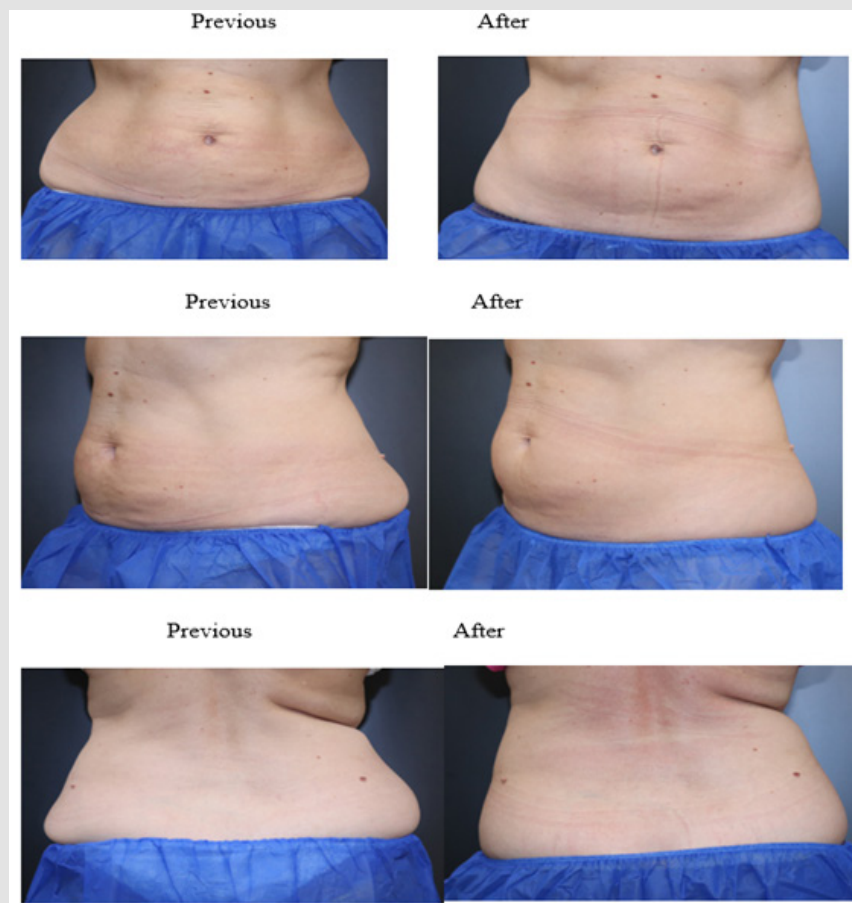


Figure 2.

Management

In order to establish a proper protocol to anticipate and propose a pharmacological assessment we present the following guide.

Instruct about the NPRS

Describe situations that produced the most pain in the patient. Grade those moment as 10 (severe). When applying the massage ask the patient to grade the sensation compared with the feeling remembered as severe.

Take in consideration when interviewing patient what kind of person we are going to deal with regarding pain, as susceptibility to pain is very much personal an intriguingly it may even have a large heritable component [10].

Pharmacological Treatment

Oral

Pain:

- Acetaminophen: 0,5- 1 g every 4-6 h. Maximum 4 g per day.
- Acetaminophen / Tramadol hydrochloride (325 mg/37,5 mg): 2 tablets up to every 6 hours. Maximum 8 tablets per day.
- Tramadol hydrochloride: 50-100 mg every 4-6 h. Maximum 400 mg per day
- Alternative to pain killers
- Gabapentin: initially 300 mg once daily for day 1, then 300 mg twice daily for day 2, then 300 mg 3 times a day for day 3. Adjust according to response up to a maximum of 3.6 g per day.
- Pregabalin: initially 150 mg daily in 2-3 divided doses. Then increased if necessary to 300 mgrs daily in 2-3 divided doses.

Anxiety:

- Buspirone hydrochloride: 5 mg 2-3 times per day, increased if necessary up to 45 mg daily.
- Alprazolam: 250-300 micrograms 3 times a day increased if necessary up to 3 mg daily.

Insomnia (Short Term Use and to be Taken at Bedtime):

- Midazolam: 7,5 mg daily
- Lorazepam: 1-2 mg daily
- Zolpidem tartrate: 10 mg daily

Topical:

- Lidocaine 2,5% plus prilocaine 2.5% cream: apply 10 g for 10 minutes.

- Fentanyl transdermal: Initially 12 µg / 72 h, alternatively 25 µg / 72 h. Common side effects: nausea and constipation.

Have in Mind

- Administrating painkillers prior to treatment in those patients we have the feeling after the interview might have a hypersensitivity to pain.
- Make sure to be available if patient need assessment.
- Consider for those cases of severe pain the transdermal option as it will cover pain sensation for 72 h and it's a secure easy way to deal with pain.

Conclusion

This case shows the presentation of what we can include into a late onset pain associated with Cryolipolysis. Considering it's not a very common effect we have to point out it's not an isolated case and we have presented it in order to set a starting point to gather more information when using the Cool Smooth Pro Applicator. Given the complexity of pain we encourage sharing similar case reports to provide a better insight as well as develop and standardize more accurate procedures. It's essential to find the moment and time to deal with the patient expectations as well as to inform appropriately before treatment about the characteristic of the pain in case of its manifestation. Pain sensation though may be minimal most of the times, can also rise in a more intense way, but it will resolve quickly. It's a symptom for which the CoolSculpting® team have to be aware of and assist patients providing with information in such a way that they wouldn't fear the treatment but feel secure. It's a symptom that will be resolved eventually without any kind of sequelae. When using the Cool Smooth Pro Applicator the massage is felt more distressful. After 48-72 h the severity of the pain may increase to the point of hypersensitivity (dysesthesia / hyperesthesia referred as severe pain with stabbing or burning sensation) and interfere with normal live activities. It's then required to apply the therapeutical measures needed. If we anticipate its debut, we can provide a basic analgesic treatment even before applying the Cool Smooth Pro Applicator.

Author Contributions

Conceptualization, D.C.R.-V.; methodology, D.C.R.-V and I.M.-P. ; validation, M.S.-B., and E.R.-F.; formal analysis, D.C.R.-V.; investigation, D.C.R.-V., and C.J.-N.; resources, D.C.R.-V., M.S.-B., and E.R.-F.; data curation D.C.R.-V., and I.M.-P.; writing-original draft preparation, D.C.R.-V.; writing-review and editing, I.M.-P. , and C.J.-N. ;supervision, E.R.-F., and M.S.-B.; All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki.

Informed Consent Statement

Informed consent was obtained from the subject involved in the study.

Data Availability Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Conflicts of Interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the

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