

Intralipotherapy Patient Satisfaction Evaluation Study (IPSES)

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ABSTRACT

Intralipotherapy represents an injection technique specifically studied for an appropriate and rational use of injectable solutions with an adipocytolytic activity. The injection protocol, introduced in Italy in 2002 by P. Motolese is now widespread throughout Europe and is highly standardized and rigid with only small variations, which are related to the composition of the solution being injected.

The main purpose of this study is to analyze patient satisfaction when undergoing an intralipotherapy treatment. Secondary: assess whether satisfaction increases or not when performing a second intralipotherapy session. Patients are very satisfied with the results of intralipotherapy treatments and are even more satisfied after performing a second session.

KEYWORDS: Intralipotherapy, patient satisfaction, Adipocytolyses, Localized Adiposities, Aqualyx®

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INTRODUCTION

The non-surgical treatment of localized adiposity underwent a fundamental evolution around the year 2000 thanks to the off-label use of the pharmaceutical Lipostabilâ (Sanofi-Aventis)⁽¹⁾, which is no longer in production, and the subsequent introduction to the market of the injectable solution called Aqualyx®

(Marllor International). The injection protocol called intralipotherapy was proposed by P. Motolese in 2002 in relation to the mechanism of action of Lipostabilâ, erroneously interpreted initially as lipolytic^(2,3).

The presence of a localized inflammatory reaction (1), the poor receptor sensitivity to lipolytic stimuli particularly at the level of

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the trochanteric region⁽⁴⁾ and the remote possibility that the phospholipids, notoriously known for their capacity to repair and contribute to the formation of the cell membranes⁽⁵⁾, and the possibility is very remote that the phospholipids, notoriously known for their capacity to repair and contribute to the formation of the cell membrane, could also have a role of signalling hormone to activate the lipolytic process⁽⁶⁾, indicated a different mode of action of the drug. The presence of a detergent, sodium deoxycholate in the formula of Lipostabil® testifying to a lytic action of the latter on the cell membranes. An *ex vivo* histological study conducted by G. Salti e P. Motolese (data not published in the literature) shows the adipocytolytic action induced by injectable solutions containing molecules with a detergent activity, which becomes even more intense with the subsequent application of external ultrasound.

The injection intralipotherapy protocol was born as a result of understanding the mechanisms of action of these injectable solutions and provides a rigid standardized technical approach that guarantees a homogenous distribution of the solution in adipose tissue without involving the deepest muscle layer and the superficial dermal plane as is the case with the mesotherapy (intradermotherapy) technique⁽⁷⁾.

MATERIALS AND METHODS

Twenty-six (26) volunteers were included in this study. All of them were women between eighteen and sixty years old, with no systemic pathologies, taking no medications,

not pregnant nor lactating and with no other specific intralipotherapy contraindications. All subjects had a BMI index ($IMC = \text{weight}/\text{height}^2$) between 24 and 28 at the beginning of the study.

From 30 days prior to the first session until 21 days after the last Intralipotherapy session, the subjects were committed not to undergo any local nor general fat reduction treatment, including: low caloric diets, lipocryolysis, fat reducing oral products, liposuctions and other surgical procedures, mesotherapy, or carboxitherapy.

Experimental groups.

The study group consisted of twenty-six women ($n=26$). 20 were treated in Spain and were randomly assigned to one of two groups each consisting of 10 subjects, the remaining 6 were treated in Italy. All subjects received the same treatment, however each group received a different number of sessions. Subjects in the first group (G1, $n=10$) received a single Intralipotherapy session, while subjects in the second group (G2, $n=16$) received two Intralipotherapy sessions separated 21 days apart.

Product.

Intralipotherapy was performed with the Aqualyx® product. Which is an aqueous solution with a microgelatinous base containing a polymer of 3:6-anhydro-L-galactose and D-galactose, buffer systems, 3-alpha-12-alpha-dihydroxy-5-beta-24-Cholanoic Acid sodium salt, physiologic solution for

injectable preparations and sodium chloride. All together these components make up the solution known as Motolese's Solution.

Specific 100 mm intra-lipotherapy Lipoinject® needles were used.

After infiltration of the subcutaneous adipose tissue using the intralipotherapy protocol, external ultrasound with Sonolyx® was applied to the treated area.

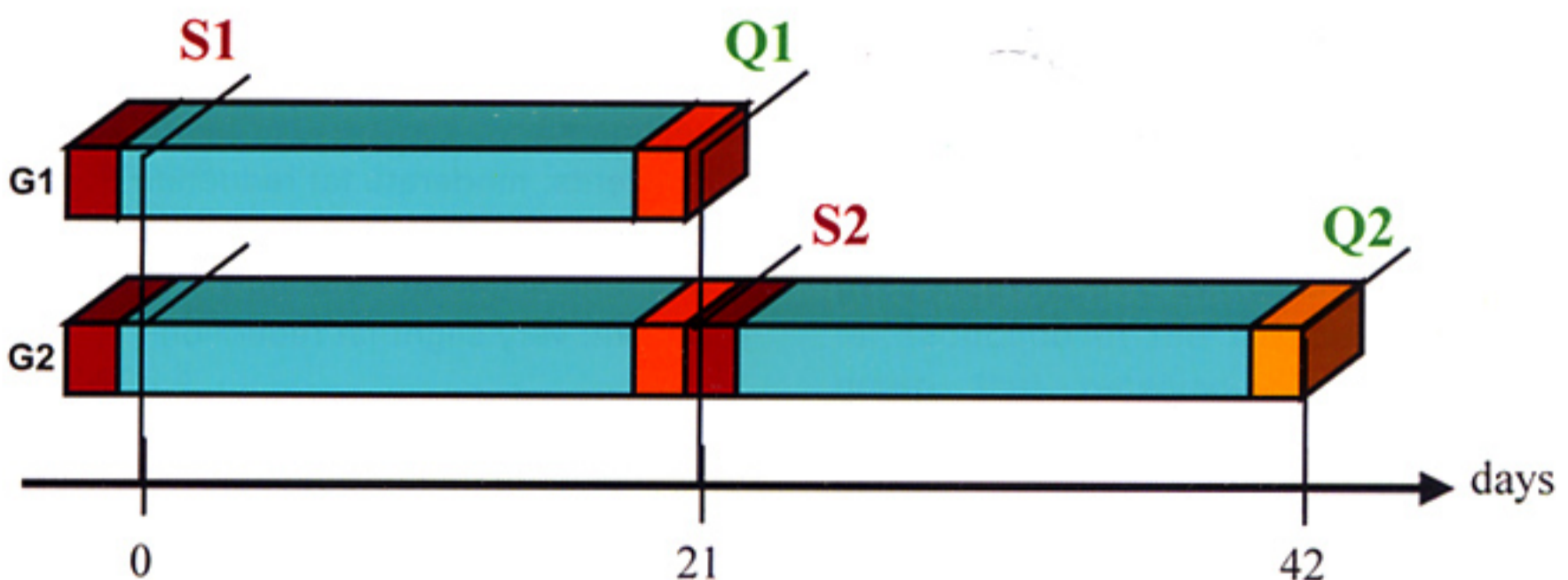
Samples.

Each participant had to fill out a self assessment questionnaire 21 days after each session. The first questionnaire (Q1) was filled out by all subjects 21 days after the first therapeutic session (S1). The second questionnaire (Q2) was filled out by G2 subjects 21 days after the second therapeutic session (S2) (Figure 1).

Each questionnaire consisted of the following questions:

1. What did you like most about this treatment?
2. What did you dislike most about this treatment?
3. Describe the results you have noticed in your body after the treatment with regards to localized fat.
4. If you received 2 therapeutic sessions, describe the differences you noticed in the localized fat of the treated area, 3 weeks after the first session and 3 weeks after the second session.
5. Would you be happy to repeat this procedure?
6. How frequently would you repeat a two to three session protocol?
7. Would you recommend this procedure to friends and relatives?
8. From 1 (no results) to 10 (spectacular results), rate the general results you saw in the treated areas.
9. From 1 (no results) to 10 (spectacular results), rate the general results you saw after the first session in the treated areas.

FIGURE 1. Questionnaire fulfilment schedule (Q1 and Q2) and sessions (S1 and S2) vs. time.



10. From 1 (no difference from the first session) to 10 (spectacular improvement comparing it to the first session), rate the results you saw after the second session in the treated areas.
11. From 1 (not satisfied at all) to 10 (absolutely satisfied), rate your satisfaction with the treatment.
12. If you received two sessions: how would you describe your satisfaction comparing it after the first session and after the whole treatment (the 2 sessions).
13. In general, would you say that this treatment reduced the localized fat in the treated area?
14. Are you satisfied with the technique and the procedure?
15. Do you think the product is relevant to achieving the results?
16. Do you think the physician is relevant to achieving the results?

Therapeutic session.

The application was divided into two zones: right and left peritrochanteric. A session consisted in the application of one and a half vials of Aqualyx® in each of these two zones according to the extension of the area to be treated and according to the posology suggested by the injection protocol. The procedure took approximately 5 minutes for every zone. The protocol used was the following:

- Indication-contraindication re-evaluation
- Informed consent signature
- Photography
- Treatment area demarcation

- Antisepsis
- Product injection
- Ultrasound application

A retrograde fan technique was used. Half a millilitre of the solution was injected with every stroke of the plunger. Two or three punctures were performed to treat a single zone according with the intralipotherapy protocol. The same physician performed all sessions.

RESULTS

Different answers to the questions posed were:

Question #1.

- 16 patients: results
- 7 patients: no pain
- 1 patient: everything
- 2 patients: physician technique

Question #2

- 8 patients: needle length
- 7 patients: "burning like" feeling when product was injected
- 4 patients: nothing
- 2 Patients: did not answer
- 4 patients: bruise (side effect)
- 1 patient: feeling the needle movement

Question #3

- 13 patients: moderate fat reduction
- 8 patients: spectacular fat reduction
- 4 patients: slight fat reduction
- 1 patient: very slight fat reduction

Question #4 (only group 2)

- 14 patients: extra fat reduction
- 1 patient: no difference
- 1 patient: did not know

Question #5

17 patients: doubtlessly
6 patients: yes
3 patients: did not know

2 patients: 3
2 patients: 8
1 patient: 9
1 patient: 6
1 patient: 4

Question#6

10 patients: every 6 months
5 patients: early
6 patients: whenever the physician advises it
3 patients: every two years
2 patients: every 3 months

Question #11

16 patients: very satisfied
8 patients: satisfied
2 patients: the treatment did not reach their expectations

Question #7

24 patients: yes
2 patients: did not know

Question #12

15 patients: the same
11 patients: increased

Question #8

11 patients: 8
5 patients: 9
4 patients: 10
2 patients: 7
2 patients: 5
1 patient: 6
1 patient: 3

Question #13

26 patients: yes

Question #9

7 patients: 8
6 patients: 7
5 patients: 5
3 patients: 9
1 patient: 10
2 patients: 6
1 patient: 4
1 patient: 3

Question #14

22 patients: yes
4 patients: no

Question #10 (group 2)

6 patients: 7
3 patients: 4

Question #15

26 patients: yes

Question #16

26 patients: yes

CONCLUSION

Intralipotherapy with Aqualyx® is a very satisfying treatment for localized adipose tissue reduction. Each subject included in this study reported the noticeable localized fat reduction in the treated areas. The group that received the second intralipotherapy reported better results than the group that received a single session. The fat reduction reported with the second session was less than the fat reduction re-

ported with the first session but was still significant.

In a very statistically significant majority, this treatment generated great satisfaction for the patients. Paradoxically, though fat reduction reported for the second session was significant, satisfaction rates did not increase proportionally. Patient satisfaction was so positively influenced by the impact of the clinical results of the first session that they kept a "very satisfied" opinion towards the procedure no matter what where the overcomes of the following sessions.

The evidence suggested that intralipotherapy is a very satisfying treatment for localized fat reduction.

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