

Newsletter

ALKANTIS study: Proof of Concept Medical Evidence - International lectures report

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Official Organ of the European Hernia Society (EHS-GREPA)
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This Newsletter N°9 reports the outcomes of the clinical study made to demonstrate the proof of the ALKANTIS Concept.

This study has been presented by Pr Champault at Orlando in the USA on March 7, 2013 during the American Hernia Society (A.H.S.) congress and later in Poland during the European Hernia society (E.H.S.) congress on May 14, 2013.

The next presentation is in Paris on June 14, 2013.

IX^{ème} Symposium
sur les prothèses pariétales
MESH 2013
Paris
14 juin 2013
Maison de la chimie

Créé par Gérard Champault
Organisé par le CLUB HERNIE
et le Chapitre Français de l'EHS

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Clinical Studies



ALKANTIS: Proof of concept

Clinical study:
Does perioperative local cooling improve outcomes after ambulatory open inguinal hernia repair?

- ✓ **Clinical study protocol**
 Randomized trials (sept 2010 to december 2011)
 - 108 patients involved
 - Ambulatory surgery
 - Two groups of patients (n=54)
- ✓ **Control group**
- ✓ **Cold therapy group: ALKANTIS**



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ALKANTIS: Proof of concept

Analgesic or Cold therapy ?



Patient's Pain	Back to the room	After 6hours
Cold Therapy only	90% no pain	70% no pain
Analgesic's injection*	76% no pain	18% no pain
* Oedema !		
Drug consumption	Day 1	Day 2
Analgesic's reduction	- 63%	- 43%

The sooner the Better !

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Sooner is Better !

Hernia (2013) 17 (Suppl 1): S25-S27

FP-4894
Does perioperative local cooling improve outcomes after ambulatory open inguinal hernia repair ?
A prospective randomized study
 Champault G
 Paris University 13, J Verdier hospital

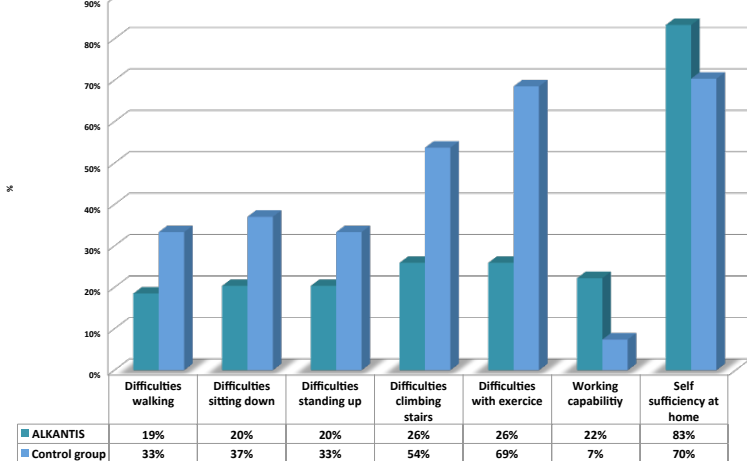
Pain and local complications are the major determinants of outcome after inguinal hernia repair.

To evaluate the respective impact of peri operative cooling of the surgical site and usual nurse care after open inguinal hernia repair, we performed a prospective randomized study 108 consecutive patients with primary unilateral inguinal hernia were included; For each patient, repair was performed by local direct access during ambulatory surgery. The first group (control) underwent standard pre and post operative local care. In the second group (cold compress group) a single use disposable sterile cold compress (Alkantis France), was applied on the the surgical site for 2 hours before and after surgery. Primary endpoints were immediate postoperative pain using a visual analogue scale (VAS) and local complications (hematoma); secondary endpoints included analgesic drug consumption, hospital stay, delay to return to normal activity, patient satisfaction.

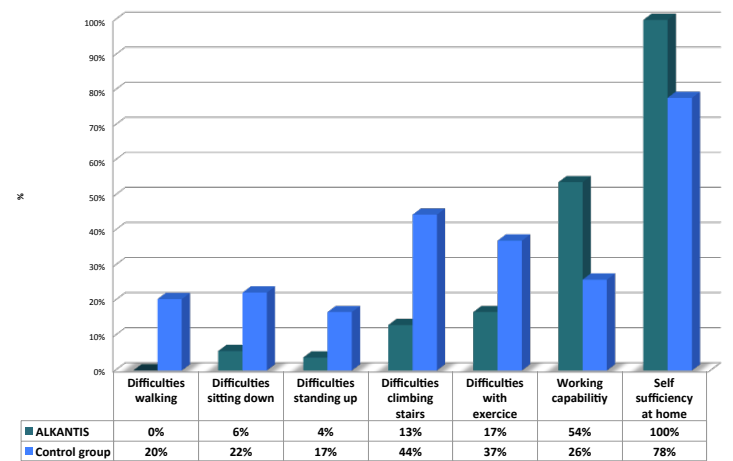
The 2 study groups were comparable with respect to pre and intra operative characteristics. There was no difference concerning operative time and early complications although there was a trend toward a reduced incidence of hematoma and ecchymosis for the cold compress group. Analgesic drug consumption was significantly (p=0.01) reduced. During the day of surgery and the first post operative day the VAS was significantly lower after cooling. There was a non significant trend toward a reduction in length of hospital stay and time to return to normal activity was shorter in the cold compress group without additional expense.

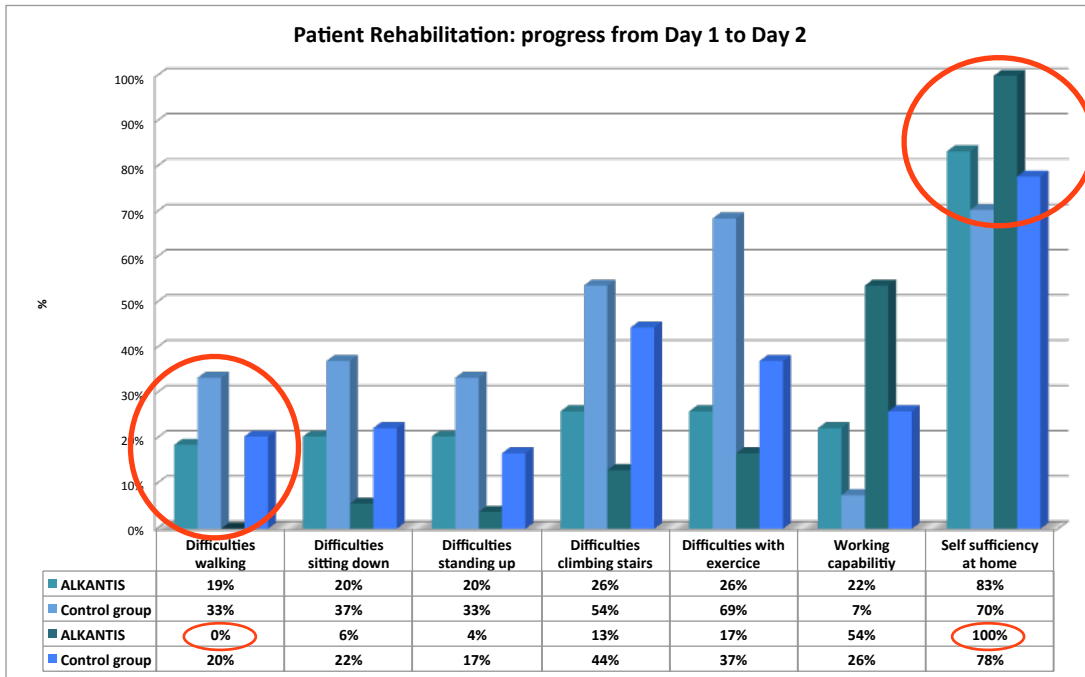
Conclusion: For open hernia repair performed in the ambulatory setting, immediate pre and post operative surgical site cooling targeting a contolled temperature between 12 and 15 °C significantly reduced postoperative pain hospital stay analgesic drug consumption and resulted in improved outcomes. This technique is safe, simple, easy to use inexpensive well tolerated by the patient.

Day1: Patient Rehabilitation



Day 2: Patient Rehabilitation





It is important to note the effectiveness of the ALKANTIS cold therapy when applied from the Operating Room.

ALKANTIS
(Ice Sterile)
Prevent rather than treat!

Conclusion

- ✓ **ALKANTIS should be perceived as an opportunity for hospitals to make savings and manage H.A.I. risks !**

HOSPITAL COSTS

Savings:

- ✓ Reduction of drugs consumption
- ✓ Helps to reduce post-operative complications
- ✓ Helps to meet hospitalization time
- ✓ Helps to reduce H.A.I.

The Sooner the better!

- ✓ **ALKANTIS is good for the Patient and good for the Hospital!**

More than a product: A CONCEPT!

The sooner the Better!

When ALKANTIS is immediately applied onto the suture line and kept in place for a period of 24 h the beneficial effects for the patient is quantifiable for the next 24H and 48 h after the surgery.

The patient feels less pain, take less medication and is able to recover more quickly.

These benefits have a real economic impact for the hospital.

Prevent rather than treat!

Results of this study apply to the other surgeries ...specialities

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Prevent rather than treat!