



# #638 Results of the use of the Harex® penis clamp

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# Fundació Puigvert

# Hypothesis / aims of study

#### Hypothesis

The Harex® penis clamp is effective in controlling post-prostate surgery urinary incontinence.

#### Objective

1.- Main objective: to study the efficacy of the Harex® penis clamp in controlling continence in patients with urinary incontinence after prostate surgery.

Efficacy will be assessed 4 weeks after using the clamp using:

- the number of absorbents required
- the ICIQ-SF questionnaire
- the Treatment Benefit Scale (TBS)
- 2.- Secondary objectives:
- Describe patient satisfaction
- Describe the ease of use of the Harex® penis clamp

## **Results and interpretation**

- The average satisfaction rate was 6/10
- Nineteen patients (73%) reported ease of use of the device
- Complications (Clavien-Dindo 1): 4 patients presented mild penile pain and 1 patient explained an hematoma in the area where the clamp was placed
- Two patients explained persistence of urinary incontinence despite the correct use of the clamp
- Accidental fall of the clamp was reported in 5 patients with retractile penis

ICIQ-SF Before	ICIQ-SF After	P value	PADS Before	PADS After	P value
17	12	p= 0.000	5,08	2,9	p= 0.005

#### **TBS**

 Describe the possible complications secondary to the use of the Harex® penis clamp

#### **Interest conflict**

The study has been financed by Mera Medical Solutions SL.

# Study design, materials and methods

- Prospective clinical research with a low intervention level
- Male patients over 18 years of age

- Stress urinary incontinence after prostatic surgery, who are offered the use of the Harex® penis clamp as a treatment option

Patients who consent to enter the study are provided with the clamp free of charge, and are instructed in its use.

These patients are evaluated 4 weeks after their use, obtaining:

- The improvement in incontinence through the TBS questionnaire and  $\ensuremath{\mathsf{ICIQ}}\xspace{-}\mathsf{SF}$
- Number of absorbents needed in 24h
- Patient satisfaction in relation to the Harex® penis clamp (0-10)
- Ease of use of the penis clamp (YES/NO)
- Record of complications using the Clavien-Dindo classification



# **Results and interpretation**

- From November 2021 to February 2023: 26 patients



### Discussion

Urinary incontinence is a recognized complication after prostate surgery, significantly affecting the quality of life of patients (1).

The penile clamp can be considered as a valid alternative to avoid or reduce the use of absorbents (2) as a temporary treatment or in non-surgical candidates.

Despite its wide use in routine clinical practice, there is little evidence to support this type of device.

This study has shown that patients who use the Harex® penis clamp have a significant reduction in the ICIQ-SF score, and in the number of pads used daily.

The results should be interpreted taking into account that they used the clamp for a maximum of 8 hours, requiring absorbents or a collector while not using the clamp.



#### Conclusions

- The mean age was 68.7 years (6.2)
- Eight patients had a history of radiotherapy (30.8%)



ORP Open Radical Prostatectomy; LRP Laparoscopic Radical Prostatectomy; RALP Robotically Assisted Laparoscopic Radical Prostatectomy; TURP Transurethral Resection of the Prostate; PVP Prostate Photovaporization



The Harex® penis clamp is an *effective and safe* device for the conservative management of urinary incontinence after prostate surgery.

#### References

1.- Vera Trofimenko, Jeremy B Myers, William O Brant. Post-Prostatectomy Incontinence: How Common and Bothersome Is It Really? Sex Med Rev. 2017; 5(4): 536-543

2.- Margaret Macaulay, Jackie Broadbridge, Heather Gage, Peter Williams, Brian Birch, Katherine N Moore, Alan Cottenden, Mandy J Fader. A trial of devices for urinary incontinence after treatment for prostate cancer. BJU Int. 2015; 116(3): 432-42