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Original Research Article

Sustained transanorectal cryogenic treatment of hemorrhoids with the cryocure device: a prospective study

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ABSTRACT

Background: Globally about 330 million people suffer from hemorrhoids at some time during their lives. About 1.2 million new cases are reported annually, it is not discussed freely and a simple, safe and cost effective solution is yet to be proposed. The authors studied a new technique called Transanorectal Vasoconstriction as a possible treatment of grade 1, 2 and 3 hemorrhoids.
Methods: The study randomly recruited 1591 patients suffering from grade 1 to 3 hemorrhoids in Europe and India and subjected them to Transanorectal Cryogenic Vasoconstriction technique using a device called Cryocure that provides sustained release cooling of hemorrhoids leading to vasoconstriction and shrinkage. The technique was applied between 7 and 15 days and patients were assessed after 3 months.
Results: The treatment outcome of 1591 patients (M:F 962:629) recruited randomly, showed that 86.12% were practically symptom free after 7 to 14 days of the treatment, and during the assessment after three months. 6.36% of the treated patients reported that one or more symptoms of itching and pain persisted but were not bleeding after the treatment period of 7 to 14 days. A few patients, 3.11% had reported that they had no benefit whatsoever from the treatment. All patients were followed for a period of 9 months. However, it was found that 4.45% of patients had various types of recurrences including bleeding.
Conclusions: The present study concludes that Transanorectal Cryogenic Vasoconstriction technique using Cryocure can be a simple, safe and cost effective choice of treatment in uncomplicated grade 1, 2 and 3 hemorrhoids.

Keywords: Cryocure, Cryogenic, Hemorrhoids, Internal and External Hemorrhoids, Vasoconstriction

INTRODUCTION

The cavernous tissue shrinks and the sphincter opens when one finds the need to pass gas or faeces, this action allows the gas or faeces to go out. In the absence of this cavernous tissue, it is difficult for a human to retain their gas and thin faeces. The sphincter cannot do this delicate and critical function on its own. This is the reason why the cavernous tissue is necessary. However, in case cavernous tissue becomes enlarged more than required and if it is also forced down due to hard pressure during defecation, it sometimes even hangs outside of the anus and bleeds; we call this as hemorrhoids or piles. So, hemorrhoids are cavernous tissue that is enlarged. The real causes cavernous tissue to degenerate into hemorrhoids is still notknown.

Possible causes include, an engineering defect in the

evolutionary design of the cavernous tissue leading to weak connective tissue under some conditions. Factors that aggregate the degeneration of cavernous tissue into hemorrhoids could be anything from too spicy food, obesity, alcohol, severe coughing, use of laxatives and other diseases of the rectum. Hemorrhoids are primarily caused by enlarged blood vessels in the rectum and anus. There are two types of hemorrhoids: internal and external. The most common complaints are blood loss, pain, burning and itching. The severity of the hemorrhoids are graded according the Banov criteria,

- Grade 1: Internal hemorrhoids that bleed but do not prolapse.
- Grade 2: Hemorrhoids which prolapse but reduce spontaneously (with or without blood loss).
- Grade 3: Are prolapsed hemorrhoids that require reduction.
- Grade 4: Are prolapsed internal hemorrhoids that cannot be reduced, usually with both internal and external components with incarcerated and thrombosed internal hemorrhoids.[1]

The prevalence in men and women aged around 50 years is more than 50%, and in pregnant women during and after delivery it is about 40%.[2,3]

METHODS

Cryocure is a specifically designed tube-like device filled with a special poly molecular cryogenic memory agent and constructed out of unbreakable medical polymer (Figure 1). It is an approved Transanorectal Cryogenic Vasoconstriction device for treatment of hemorrhoid. Cryocure device is designed to match the anatomy of the anal cavity with a length of 7 cm, to cover internal hemorrhoids and a diameter of 1.5 cm, for least trauma (Table 1).

Figure 1: Cryocure- transanorectal cryogenic device.

The device must be frozen in a freezer for two hours before use so the temperature of the device will attain a minimum of minus 18 degrees. The device is then dipped in a lubricant like coconut oil or white petroleum jelly and inserted into the anal cavity with a circular motion (to reduce muscular spasm). The patient is asked to relax when he is performing the procedure. After insertion of the Cryocure device till its base, it stays in situ for at least 10 minutes.

Table 1: Biomedical design data of the cryogenic device.

Biomedical data of cryocure	
Human internal hemorrhoids: • 4-6cm designed for internal and external hemorrhoids • therapeutic length: 7 cm sphincter function is protected, hence voluntary control over motions are preserved • Therapeutic diameter: 1.5 cm • Less energy to attain therapeutic temperature • Freezer time: 2 hours.	• Effective Vasoconstriction occurs attemperature below -12°C in sustained release • Therapeutic Temperature: -18°C • Small vessel vaso-response to temperature is 6 to 10 minutes • Sustained Thermal Release Time: >9.8 minutes at 37°C. • To prevent frost bite the moisture absorption should be less than 0.3% • Safe Moisture Absorption: <0.1%, frost bite not possible.

Cryogenic Vasoconstriction in Hemorrhoids was used in the past successfully but for the adverse effects, in spite of it being generally done in a specialized hospital setting at -196°C, the liquid nitrogen temperature. However, there tends to be more pain after the procedure and there are increased risks of infection and bleeding. Cryogenic surgery was once very common, but most physicians now opt for other treatments due to many potential complications in this procedure.[4] Effective vasoconstriction starts at a temperature of -12°C with a sustained release, but with Cryocure, we could take it upto -18°C to -20°C in a home freezer and found sufficient vasoconstriction to aid in shrinkage of hemorrhoids.

In an observational intervention study conducted between November 2016 and December 2018 in Enschede, the Netherlands and Bangalore, India 1591 patients who used the cryocure, cryogenic device were randomly recruited, based on the inclusion criteria that all of them had confirmed diagnosis of hemorrhoids in stage 1, 2 or 3. Patients with fissure ani and confirmed or suspected malignancy were excluded from the study. All of the patients had blood loss and mostly other complaints such as anal pain, burning and itching. After about 3 months the patients returned to the treatment centre and were asked about their complaints and underwent physical

examination. Patients were assessed for Blood loss, itching, pain, burning and ease of defecation.

RESULTS

Out of the 1591 patients (M:F=962:629) recruited randomly, 1370 patients were practically symptom free after 7 to 14 days of the treatment, and during the assessment after three months. One Hundred and One (101) patients reported that one or more symptoms of itching and pain persisted but were not bleeding after 3 months. A few patients (50), had reported that they had no benefit whatsoever. All patients were followed for a period of 9 months and it was found that 70 patients had various types of recurrences including bleeding (Table 2).

Table 2: Study outcome.

Total No. of patients	Numbers	Percentage
Male:Female	962:629	
Number of patients who was asymptomatic, post treatment.	1370	86.12%
Number of patients where one or more symptoms persisted.	101	6.36%
Number of patients that had reported no benefits.	50	3.11%
Number of patients in whom there was recurrence and had to use cryocure again within 9 months	70	4.41

Table 3: Symptomatic outcome.

Sustained transanorectal cryogenic treatment- Symtomatic outcome
Zero blood loss – in fact, stops bleeding Immediately.
Procedure was painless.
Hemorrhoids shrink in 10~15 days in 86.12% of patients.
Sphincter function was not hampered in any treated patients.
Recurrent rate was just 4.41%
Patient did not stop working to take treatment- there was no loss of productivity.
All patients had their treatments done at the comfort of their home.
No significant inflammation or infection was observed.
None of the patients had experienced any urgency (urge to rush to the toilet)
No adverse effects were reported in their status of diabetics, heart diseases or BP.

It was not clear, if reusing Cryocure would help these populations, or they need to find alternate ways of treatment. The general symptomatic outcome show that the patients had minimal discomfort, ease of use, no productivity loss and no adverse effects. The treatment did not alter their diabetic or blood pressure status (Table 3).

Figure 2 shows the inserted cryocure in the anal canal. The mode of action is vasoconstriction by applying cryogenic principles. The length of the Cryocure is critical, and should be around 7 cm, this is because the internal hemorrhoids are located 4-5 cm from the external sphincter.[5]

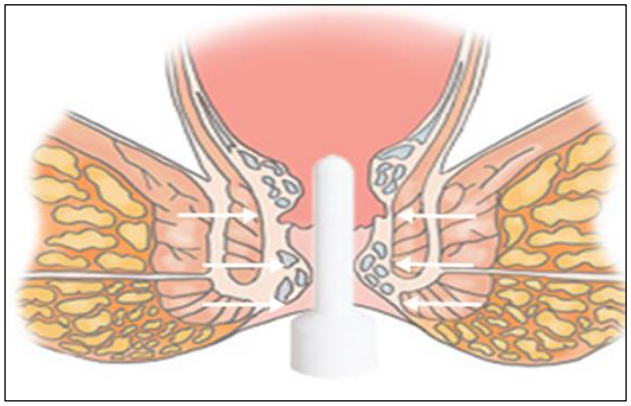

Figure 2: Sufficient time for good vasoconstriction; sustained thermal release time: >9.8 minutes at 37ºC.

DISCUSSION

It is imperative that the Cryocure insertion length has to be at least 7 cm to adequately apply the sustained low temperature to the external and internal hemorrhoids as the human internal hemorrhoid is situated 4 to 6 centimeters deep inside the anus. It is also important that the sphincter function is protected during the treatment, so that the voluntary control over defecation and degassing is preserved. For this purpose the biomedical therapeutic diameter should be between 1.4 to 1.8 centimeters. Exposure to cryogenics stimulates cold receptors of the anal wall which causes cold thermal sensations and stimulate the sympathetic nervous system. The sympathetic stimulation causes vasoconstriction in the vessels (mainly veins) of the cavernous tissue.[5,6] Cryogenically induced sustained low temperature also increases localized blood pressure and viscosity while decreasing plasma volume causing microthrombi and reduction of the blood flow which results in the shrinkage of the enlarged vessels.[7] However, this is a tricky business, too high a temperature, effective vasoconstriction does not occur; too low the temperature has other complications. The effective temperature transmission for vasoconstriction to happen is below -12°C, so ideally the cryogenic device, should be cooled between -15 to -20◦C, and this should be released very slowly to adequately stimulate the cold receptors in the anal cavity, the sustained thermal release time should be above 9.7 minutes at 37°C body temperature. When dealing with living tissue and extreme cold, there is another problem 'Frost- bite', Frostbite is an extremely

low temperature-induced injury and the term is used to indicate damage to the tissues caused by extremely low temperature freezing. The extent of damage is directly related to the temperature gradient (dt) at the point of contact and the duration of exposure.[8] The lower the temperature, the faster the tissue will freeze and cause formation of ice crystals. However, the degree of 'irreversible damage' is proportional to the period of time the tissue is in a frozen state and the moisture absorption of the frozen surface in contact with the cavernous tissue. Frostbite injuries are caused by two separate processes: The intrastecisial ice crystallization of the tissue causes cellular death and the reperfusion injury that occurs when the cold is removed and re-warming occurs in the anal cavity. The formation of ice crystals begins even when tissue temperature falls just below -2.2°C and direct mechanical damage to cell walls occurs both in intracellular and extracellular spaces. Crystallized ice in the intravascular spaces leads to a secondary mechanism of injury that damages the endothelium and causes inflammation resulting in vascular stasis, thrombosis, in the tissue leading to ischemia resulting to cell death.[9,10]

So it is extremely important that the device used for cryogenic vasoconstriction should (1) be able to release the cold sustainably over a period so that the temperature does not fall below -2.2°C at any time during the 10 minutes anal retention period (2) The safe moisture absorption of the frozen device coming in contact with the tissue should not be more than 0.3%. In the Cryocure device used here, the sustained release temperature was -1.8 to 2.0°C over a period of 10 minutes, this is the reason why the device have to be retained in the anal cavity for a minimum period of 10 minutes. The moisture absorption of the Cryocure device is less than 0.1%, much less than injury causing moisture absorption of 0.3%. Thus, the Cryocure device is extremely safe for self-use by the patient himself in a home setting.

This also qualifies that cryogenic vasoconstriction should be very useful in the section of population like the members of the armed forces, police etc, who are in the field work and cannot be hospitalized for surgical procedures for hemorrhoids. Sustained Transanorectal cryogenic treatment using the cryogenic device can be safely used in defense camp.[11] Considering its ease of use, safety and patient compliance, the Cryocure device can be used after other procedures employed to treat Hemorrhoids like the rubber band ligation, where it is reported that 25% of the patients could get enormous pain relief. Cryocure device should also find application in relieving pain in patients post Hemorrhoidectomy.

CONCLUSION

Uncomplicated grade 1, 2 and 3 hemorrhoids can effectively be treated with the Cryocure device. As the Sustained Transanorectal Cryogenic Treatment using Cryocure device is safe with no bleeding, pain, hospitalization, low risk of infection and inflammation with no side effects, thus it must be considered as first line treatment for grade 1, 2 and 3 hemorrhoids patients. Since it is safe for diabetic and heart patients, one more application could be to treat anal bleeding of patients due to hemorrhoids during management of sick patients in the ICU/CCU. It has been reported that about 40% of the pregnant women during and after delivery suffers from hemorrhoids; use of Cryocure device could bring great relief without compromising the safety of the mother or the child.

The conclusion would not be complete; if the issue of hemorrhoid induced loss of productivity is not discussed. In the occupational health, people employed in the modern day computer/information technology 'factories' where long squatting, food and other aggravating factors have increased the incident of hemorrhoids many folds. It is also reported that occurrences of Hemorrhoid and related problems are large among the members of the Armed Forces. This population, who cannot be hospitalized for a surgical procedure for hemorrhoids, when in the field, should also consider using Sustained Transanorectal Cryogenic Treatment using the Cryocure device that can be used in most defense camps. This also applies to other essential profession like Police, Paramedics, firemen etc.

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