



Research Project RP09-04

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Research project plan EAUN Stockholm 2009

How to instruct patients on the use of a vacuum device for the management of their erectile dysfunction (ED).

Introduction

Andros Men's Health Institutes, a private healthcare initiative, are created to provide adequate preventive and early diagnostic urological and urogenital healthcare for the ageing male. These institutes see many patients with erectile dysfunction and for some of them a vacuum device is the final solution for the management of their ED. The information, instruction and follow-up care of the vacuum device is delegated to the nursing team of these Men's Health Institutes.

Recently, amongst the nurses a discussion originated on the issue of how to instruct the patient on the use of the vacuum device. Upon choice of this treatment, the patient has to be instructed by the nurse in a ½-hour informative session. Some nurses prefer a theoretical explanation on the use and mechanism of the vacuum device with the aid of a model (theoretical way), whereas other nurses prefer physically demonstrating the mechanism of the vacuum device on the patient (direct way). However, until now it is still not clear which way is the most effective for the patient *and* which way is preferred by the patient.

Objectives

The objective of this study is to define the most effective way of providing patient friendly information and instruction by the nurse practitioner on the use of the vacuum device.

In the study, the research objectives are:

1. acquiring clarification on the amount of effectiveness of both instruction methods of the vacuum device;
2. obtaining more information on the preference of the clients (patients) on:
 - a) how does the patient judge the effectiveness of the instruction?
 - b) what does the patient think of the direct way of demonstration?

Background

Erectile dysfunction as defined by the World Health Organisation is a frequently encountered problem, and is defined by the WHO as: *the impossibility to obtain and maintain a sufficient erection for satisfying sexual activity.*

A recent investigation in The Netherlands on the prevalence of erectile dysfunction demonstrated that

1. as of the age of 18 and older 16.8% of the men suffer from erectile dysfunction
2. the higher the age, the higher the chance of erectile dysfunction
3. more than 40% over the age of 60 are suffering from erectile dysfunction (de Boer et al, 2001).

On an annual basis, the Andros Men's Health Institutes see about 5.000 patients for preventive and early diagnostic advice related to their urological and urogenital system. At least 50% of those patients have complaints of erectile dysfunction. Most of these patients are treated with drugs, such as PDE5 inhibitors. For some patients drugs are not an option:

1. in case of no responsiveness to these drugs (e.g. patients with diabetes mellitus type 2 or men after radical prostatectomy)
2. in case of contra-indication (e.g. patients with cardiac problems) or side effects of the medication (headache, flushing, vision disturbances, agitation).

Alternative treatments for erectile dysfunction are:

1. intracavernous self-injections with papaverine/phentolamine (androskat)
2. inducing erections with a vacuum device

However, there are absolute contra-indications for intracavernous self-injections such as the use of anticoagulants or the desire for frequent sexual activities (androskat may only be injected once a week). For these patients a vacuum device can be the most reasonable alternative.

Within the Andros Men's Health Institutes we use the AES vacuum device. Clients can either buy the device or rent it for some weeks. Before the use of the device by the client he receives an extensive instruction from an experienced nurse. Moreover, the patient receives a brochure with information and the referral to a website with an instruction video, which can be watched at home.

The experience of the Andros Men's Health Institutes' nurses is that sometimes the acceptance of the device is a difficult issue for the patient and his partner. A lot of information is needed before this device is accepted as an alternative treatment for the erectile dysfunction. In this respect, the way of information and instruction is of essential strategic importance. The aim of the information is to instruct the patient in such a way that he feels comfortable with the use of the device and will indeed use it in a satisfactory way. So far, the information has been given at random depending on the preference of the nurse. Some nurses prefer giving just theoretical information, where other nurses prefer to give physical instruction to the patient by directly applying the device and as such inducing an erection during the information session.

Methods

The objective of the study will be investigated in 2 parts, i.e. a retrospective part and a prospective part.

1. The retrospective part will consist of an evaluation of a patient groups who have already received either the theoretical instruction or the direct demonstration, and who are still using the device. The evaluation will be done by means of a questionnaire (attachment 1), which will be sent to the users of the vacuum device with the request to fill out all questions. The outcome of the questionnaires will then be compared. After having filled out the questionnaire, the patient will also be interviewed by the research nurse. In this interview the nurse will discuss the answers with the patient and she will justify and rate and grade of the patient's satisfaction and the effectiveness of the device. The group consists of 30 patients, of which approximately half have received theoretical information, and another half have had a direct (physical) demonstration.
Comparison of the data in the two groups will answer the question as to which information method is preferred most by the patient and his partner.
2. The prospective evaluation will contain patients selected for the use of the device during the period of 1 year (January 2009-January 2010). They will be randomly assigned to the group of theoretical instruction or direct demonstration. After the information the appreciation of the patient will be registered through a satisfaction

questionnaire (attachment 2). Each group will be allotted 25 patients. 6 months after the initial information, the satisfaction effectiveness of the information and the use of the device will be evaluated through the same questionnaire and interview as used in the retrospective evaluation (part 1) of the research plan.

Inclusion criteria

- Retrospective evaluation, 30 patients who already received a device in the current year will be evaluated.
- Prospective evaluation, 50 patients to whom a device is prescribed as the preferred treatment for the erectile dysfunction will be eligible for inclusion in the study.

Exclusion criteria

1. Insufficient knowledge of the Dutch language for filling in the questionnaire.
2. Insufficient motivation to fill in the questionnaire.

Timeline

Retrospective part:

Mailing of the questionnaires	February 2009
Evaluation of the questionnaires	March/ April 2009

Prospective part:

Inclusion of patients	January – December 2009
Mailing of the questionnaires	June 2009- June 2010
Evaluation of the questionnaires	July 2009-July 2010

Budget

Salary personnel	€1250,-
Mailing costs	€250,-
Administration costs	€500,-
Interview costs	€500,-

Conclusion

The study will give an answer to the question on which form of information is most appreciated and effective for patients who will use a vacuum device as treatment option for their erectile dysfunction. Therefore it will help the Andros Clinic to develop a protocol regarding this issue, based on Evidence Based Practice.

Moreover, the study will evaluate the satisfaction of the use of the device in relation to the form of initial information. The outcome of the study will be important for future methods of information and instruction to patients in order to improve the acceptance of a vacuum device in the management of erectile dysfunction, something that is still very ambiguous for patients suffering from erectile dysfunction and their partners.