A Pilot Study to Determine Penile Oxygen Saturation Before and After Vacuum Therapy in Patients with Erectile Dysfunction After Radical Prostatectomy

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DOI: 10.1111/jsm.12445

ABSTRACT

Introduction. Provoked and spontaneous nocturnal erections are thought to play a role in maintenance of male sexual health through oxygenation of the corpus cavernosa. Conversely, hypoxia is thought to be an etiological factor in the pathogenesis of cavernosal fibrosis and long-term erectile dysfunction. It has been hypothesized that the early penile hypoxia after radical prostatectomy (RP) may lead to fibrosis and consequently a decrease in stretched penile length and long-term erectile dysfunction.

Aim. The aim of this study was to assess the changes in penile tissue oxygenation with vacuum erection device (VED) use.

Methods. Twenty men between 2 and 24 months following RP were enrolled prospectively. Each man cycled a VED to achieve full erection 10 consecutive times over a period of approximately 2 minutes without constriction ring.

Main Outcome Measures. Tissue oximetry was measured at baseline and immediately after VED using a tissue oximeter at five sites: right thigh, right corpora, glans, left corpora, and left thigh. Additional measurements were captured over the course of an hour.

Results. Mean age and time from surgery was 58.2 years and 12.6 months, respectively, and the average Sexual Health Inventory for Men score was 7. Use of the VED significantly increased both glanular and corporal oximetry relative to the baseline values for the entire 60 minutes. An initial increase of 55% was seen in corporal oxygenation with VED use.

Conclusions. This is the first study demonstrating that a single, brief application of the VED without a constriction ring results in significant improvement in penile oxygen saturation. The use of a VED has significant benefits for patients both with regard to cost and invasiveness when compared with other penile rehabilitation protocols.

Welliver RC Jr, Mechlin C, Goodwin B, Alukal JP, and McCullough AR. A pilot study to determine penile oxygen saturation before and after vacuum therapy in patients with erectile dysfunction after radical prostatectomy. J Sex Med 2014;11:1071–1077.

Key Words. Erectile Dysfunction; Oximetry; Vacuum Erection Device; Penile Rehabilitation; Prostate Cancer; Radical Prostatectomy

Introduction

Radical prostatectomy (RP) is a common treatment for localized prostate cancer. Despite nerve sparing prostatectomy and the magnification allowed by robotically assisted laparoscopic approach, true preservation of erectile function is rare. Most men will experience some degree of erectile dysfunction (ED) after RP. The etiology of the long-term ED is thought to be a combination

of nerve and vascular injury with secondary cavernosal apoptotic myopathy. Even after nerve sparing prostatectomy, there is an immediate loss of nocturnal penile tumescence (NPT) and generally a refractory period where erectile function is lost [1].

In previous animal and human studies of cavernous nerve injury, early corporal fibrosis has been demonstrated after RP [2–4]. With this nerve injury and the disruption of both provoked erections and normal NPT, there is a prolonged hypoxemic state leading to fibrosis [5]. Penile hypoxia and fibrosis in Vignozzi's [6] bilateral cavernous nerve ablation rat model was noted with sildenafil administration improving this hypoxic state. In summation, these studies point toward a correlation with cavernous nerve injury, hypoxia, and increasing damage to the corporal tissue while in this hypoxic state.

Early postoperative therapy with intracavernosal injection (ICI) of prostaglandin E-1 was the first pharmacologic intervention to have demonstrated a beneficial effect on the return of erectile function [7]. After this seminal work was published, there was an increased interest to preserve erectile function using pharmacologic treatments. The theory behind these treatments was that ICI allowed an increase in oxygenation in the corporal tissue with a subsequent decrease in fibrosis. Based on these findings, numerous penile rehabilitation strategies have been described including the use of phosphodiesterase type 5 inhibitors (PDE5is), ICI, intraurethral alprostadil (IUA), steroids, and the vacuum erection device (VED) [8–10]. Currently, there is no consensus as to the preeminent rehabilitative regimen although the VED was the second most commonly used in a recent survey of American Urological Association members [11].

The VED is the only non-pharmacologic strategy among these choices and has recently undergone resurgence as a treatment for ED [12]. In 2006, the Food and Drug Administration (FDA) granted extended labeling for the VED indicating that the product could be used to create and maintain erections by providing arterial blood to the penis during recovery from prostatectomy and thus aid in maintaining preoperative sexual function. This was the first device or drug to be cleared by the FDA for this specific indication. Despite its approval by the FDA for penile rehabilitation after RP, there have never been any studies demonstrating improved penile oxygenation with the VED. An earlier study concluded that VED use (with constriction band) may actually lead to a relatively hypoxic state [13]. Nonetheless, contemporary studies using VED in early penile rehabilitation have shown improvement in preservation of penile length after RP as well as some benefit in the return of erectile and sexual function [14–16]. An animal study provided some insight into this problem as mice underwent VED therapy for 4 weeks after bilateral cavernous nerve injury. The use of a VED preserved markers of erectile function through avoidance of antihypoxic and antifibrotic pathways [17]. In another study looking at VED use in mice after nerve injury, the benefits to cavernous blood oxygenation were demonstrated [18]. Despite these encouraging findings, there are no standard protocols for VED use especially with respect to the daily frequency/duration or length of rehabilitation.

We undertook a pilot study to examine the short-term effects of VED on penile oxygenation and possibly show a physiologic rationale for the use of the VED in men after RP. We hypothesized that these men would have a significant increase in penile oxygenation with the use of VED.

Material and Methods

Twenty men with normal preoperative erectile function were recruited after RP. Institutional review board approval was obtained at the senior author's institution at the time of the study. Excluded subjects included those with a significant history of cardiovascular disease in the last 6 months, those with any anatomical penile deformity, any disease contraindicating the use of PDE5is, and those that had used erectogenic aids within 7 days of the screening visit. The subject self-administered the Sexual Health Inventory for Men (SHIM) before RP and at time of study entry. All men had normal erectile function (SHIM >21) before RP. All surgeries were performed with the open, bilateral nerve sparing technique by the same surgeon.

Under supervision by the study nurse, the men were instructed on VED use to achieve a visually maximum erection. The men then cycled the VED 10 times over an approximately 2-minute period while under supervision of the study nurse in office. No constriction ring was used during the device cycling or at any point in the study. The 2-minute period was chosen as a practical point as men are in the habit of brushing their teeth for a 2-minute period twice daily. By using the VED in