The Who, How and What of Real-World Penile Implantation in 2015: The PROPPER Registry Baseline Data

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Purpose: To date, the published data on patients treated with penile implantation generally consist of small series of single surgeon, retrospective experiences rather than prospective or large, multicenter evaluations. This study establishes a baseline of data collection from the PROPPER (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration). The PROPPER is the first large, prospective, multicenter, multinational, monitored, and internal review board approved study of real-world outcomes for patients with penile implants.

Materials and Methods: Data from the PROPPER study were examined to determine patient baseline characteristics and primary and secondary etiologies before treatment of erectile dysfunction. Data include type and size of implant received, surgical steps/techniques used during implantation, and duration of hospital stay.

Results: Through April 2, 2015 a total of 1,019 patients were enrolled in the study at 11 sites, with radical prostatectomy being the predominant etiology in 285 (28%). Of those 285 patients treated with radical prostatectomy 280 (98.2%) received an AMS 700™. Of these patients 65.0% (182 of 280) had placement of the reservoir in the traditional retropubic space vs 31.8% (89 of 280) in a submuscular location. Of those patients not treated with radical prostatectomy receiving an AMS 700, fewer underwent reservoir placement in the submuscular

Abbreviations and Acronyms

AMS = American Medical Systems

ED = erectile dysfunction

IPP = inflatable penile prosthesis

OR = operating room

PROPPER = Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration

RP = radical prostatectomy

SUI = stress urinary incontinence

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location (17.7%, 124 of 702, vs 80.9%, 568 of 702; p <0.001). Of those patients receiving an AMS 700, those treated with radical prostatectomy and those with diabetes had more outpatient admissions (less than 24 hours, 56.8% and 52.1%, respectively) compared to those with cardiovascular disease and Peyronie's disease (42.0% and 35.6%, respectively, p <0.001).

Conclusions: This first-of-its-kind, large, prospective, multicenter study reveals most penile implant cases in North America receive an inflatable penile prosthesis and that radical prostatectomy is the most common primary etiology of penile implant surgery. Moreover, patients treated with radical prostatectomy were more likely to have the reservoir placed in a submuscular location, have a longer operating room time and be admitted to the hospital overnight compared with other patient groups.

Key Words: registries; penile prosthesis; impotence, vasculogenic; erectile dysfunction; surgical procedures, operative

HISTORICALLY, early surgical treatment for erectile dysfunction involved the placement of rigid devices extracorporally. This practice resulted in high rates of erosion and infection. Advancements in biomaterials and surgical techniques have led to most U.S. urologists placing an inflatable penile prosthesis with an infection retardant coating inside the corpora cavernosa. To date, the published data on patients with penile implants consisted mostly of small series of single surgeon, retrospective experiences rather than a prospective, large, multicenter evaluation.[1–5] Indeed, this endeavor does not have many registries with which this study can be compared, particularly in the context of a urological surgery study.[6–10] A desire for a large advocacy study in the field of surgical men's health led to the creation of the PROPPER.

In addition to changes in the type of implant used, surgical techniques have evolved greatly in recent years, resulting in reduced operating times, lower infection rates and improved outcomes.[11] For the first time in the published literature, this study includes a comparison of penile prosthesis implantation techniques used and provides data on followup care, such as when patients went home and whether they were discharged home with or without a catheter. Moreover, the PROPPER study may be used for future Food and Drug Administration labeling changes, as several commonly used surgical techniques currently constitute off label use.[12–18]

We report the first prospective, multicenter, international, large cohort evaluation to determine baseline characteristics of patients with penile implants. Surgical outcomes, complications and followup data are not presented in this baseline study. However, our study plan will yield multiple reports revealing these future data points. This clinical study entitled, "Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration" (PROPPER) collects real-world data for patients undergoing penile implantation surgery.

MATERIALS AND METHODS

Data from the PROPPER study were examined to determine patient baseline characteristics, primary and secondary etiologies, prior ED treatment, type and size of implant received, surgical techniques during implantation and duration of hospital stay.

PROPPER Study Objective and Design

PROPPER (clinicaltrials.gov identifier NCT01383018) collects data for patients treated with AMS 700, AMS Ambicor™ and AMS Spectra™ penile implants. AMS sponsors the study and only AMS penile implants were included in the study. PROPPER was designed to quantify penile prosthesis durability, complications and effectiveness, which includes patient reported functionality, satisfaction and quality of life outcomes. Patients scheduled for penile implantation were invited to participate in the study if they were so willing, and these patients provided informed consent for study enrollment. Internal review board approval was obtained at all sites and the study consent process was conducted according to site requirements.

The PROPPER registry was initiated in June 2011 with 14 sites initially agreeing to participate. Current patients with AMS penile prostheses continue to be enrolled at 11 North American sites. Preoperatively the physician investigators recorded baseline patient characteristics such as age, penile measurements and primary etiology, and patients completed the IIEF-5 (International Index of Erectile Function-5)/Sexual Health Inventory for Men, SF-12 Health-Related Quality of Life Questionnaire, Erectile Hardness Questionnaire, AUA-SI (American Urological Association Symptom Index) and UCLA-PCI (Prostate Cancer Index) Questionnaire. Surgical techniques evaluated included drain use, Foley use, dressing use, suture use, technique for closing corporotomy, and equipment and technique for corpora dilation. Surgery type included original, revision/replacement, salvage and replacing into a previously explanted corpora.

At followup, which extends from 1 to 5 years after implant, patients are asked 2 standardized questions to assess device use and satisfaction, including whether they use the device and, if used, with what frequency. This satisfaction question is gauged on a 5-point Likert scale (with responses "very satisfied," "satisfied," "neither satisfied nor dissatisfied," "dissatisfied" and "very