Original Article

Comparison of patient satisfaction rates for the malleable and two piece-inflatable penile prostheses

Malleable ve iki parçalı şişirilebilir penil protezlerin hasta memnuniyetleri açısından karşılaştırılması

Hakan Kılıçarslan[1], Yurdaer Kaynak[2], Kaan Gökcen[3], Burhan Coşkun[1], Onur Kaygısız[1]

ABSTRACT

Objective: To compare patient/partner satisfaction with AMS 600-650 and AMS Ambicore penile implants (American Medical Systems, Minneapolis, USA) in patients with erectile dysfunction.

Material and methods: The modified Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaires at six months after implantation of 46 patients who underwent AMS 600-650 (n=23) or Ambicore placement (n=23) between 1/1/2008 and 1/1/2013 were analyzed.

Results: The percentages of patients with AMS 600-650 who reported to be satisfied, very satisfied and neither satisfied nor dissatisfied with their prostheses were 34.78% (n=8), 30.43% (n=7) and 34.78% (n=8), respectively. For patients with AMS Ambicore, these percentages were 73.91% (n=17), 13.04% (n=3) and 13.04% (n=3), respectively. These overall satisfaction rates were significantly different between patients with AMS 600-650 and Ambicore (p=0.013). For patients with AMS 600-650, the percentages of patients who reported to be very likely, neither likely nor unlikely, or very unlikely to continue using their prosthesis were 30.43% (n=7), 34.78% (n=8), and 34.78% (n=8) while for patients with AMS Ambicore, these percentages were 65.21%, 21.33%, and 13.04%, respectively. These percentages were different between patients with AMS 600-650 and Ambicore (p=0.018).

Conclusion: The two-piece inflatable penile prosthesis was found to be more successful in overall satisfaction and more likely for continued use when compared to the malleable penile prosthesis.

Key words: Erectile dysfunction; patient satisfaction; penile prostheses.

ÖZET

Amaç: Ereksiyon bozukluğu olan hastalarda, AMS (American Medical Systems, Minneapolis, ABD) 600-650 ve AMS Ambicore penil implantların hasta memnuniyetlerinin karşılaştırmak.

Gereç ve yöntemler: Ocak 2008-2013 arsında AMS 600-650 (n=23) veya Ambicore penil implant yerleştirilmiş 46 hastanın operasyon sonrası 6. aydaki modifiye EDITS (The modified Erectile Dysfunction Inventory of Treatment Satisfaction) sorgulamaları analiz edildi.

Bulgular: AMS 600-650 ile implantasyon yapılan hastalardan, protezlerinden çok memnun, ne memnun ne de değil ve memnun olmadıklarını ifade edenlerin oranları sırasıyla %34,78 (n=8), %30,43 (n=7) ve %34,78 (n=8) idi. Bu oranlar AMS Ambicore için sırasıyla, %73,91 (n=17), %13,04 (n=3) ve %13,04 (n=3) idi. AMS Ambicore ve 600-650'nin toplam hasta memnuniyet oranları istatistiksel olarak farklı idi (p=0,013). AMS 600-650 implantasyonlu hastalarda, protezlerini büyük olasılıkla kullanmaya devam edecekler, kararsız olanlar ve kullanmayacakların oranları sırasıyla %30,43 (n=7), %34,78 (n=8) ve %34,78 (n=8) iken AMS Ambicor implantasyonlu hastalarda bu oranlar sırası ile, %65,21, %21,33 ve %13,04 idi. Bu oranlar AMS Ambicore ve AMS 600-650 implantasyonu yapılmış hasatlarda istatistiksel olarak farklı idi (p=0,018).

Sonuç: İki parçalı şişirilebilir penil protez malleable penil proteze kıyasla, daha çok hasta memnuniyeti oluşturur ve hastalar tarafından kullanılmaya devam edilmesi daha olasıdır.

Anahtar kelimeler: Ereksiyon bozukluğu; hasta memnuniyeti; penil protezler.

[1]Department of Urology, Uludağ University Faculty of Medicine, Bursa, Turkey

[2]Department of Urology, Eskişehir State Hospital, Eskişehir, Turkey

[3]Department of Urology, Osmaniye State Hospital, Osmaniye, Turkey

Submitted: 09.07.2014

Accepted: 21.08.2014

Correspondence: Yurdaer Kaynak, Department of Urology, Eskişehir State Hospital, Eskişehir, Turkey
Phone: +90 222 237 48 00
E-mail: yurdaerkaynak@hotmail.com

Available online at www.turkishjournalofurology.com

Introduction

Surgical implantation of a penile prosthesis is a treatment option for patients with erectile dysfunction due to an organic cause and who are unwilling to consider, fail to respond to, or cannot continue with medical treatment or external devices.[1-3] Penile prosthesis implantation is a safe and effective treatment modality with high patient satisfaction rates.[4]

Turkish Journal of Urology 2014; 40(4): 207-10
DOI:10.5152/tud.2014.37108

Penile prostheses available in the market include one-piece malleable and two- and three-piece inflatable versions. Each type of penile prosthesis has its own advantages and disadvantages. Malleable prostheses are less expensive, easier to use and less likely to fail mechanically compared to inflatable prostheses. However, complete penile detumescence cannot be achieved with malleable implants, and this may be an important factor for patient satisfaction.[5,6] Although inflatable prostheses permit penile flaccidity and have a better functional result, not all patients are able to use this device due to lack of dexterity.[7] Patient satisfaction is closely associated with patient expectations and the performance of the implanted prosthesis.[8] Thus, making a shared decision by the clinician and the patient together on choosing which implant to use is important to improve patient satisfaction.

Three-piece inflatable penile implants are currently the most commonly implanted prostheses, and many studies have reported good patient satisfaction rates.[1,3,7,9] However, both the malleable and two-piece penile implants may be indicated in selected patients who are not appropriate for the three-piece inflatable implants due to the various reasons previously mentioned.[9] However, few studies have investigated the partner's satisfaction with the two-piece inflatable and malleable penile prostheses.[1,9]

The aim of this study was to compare patient/partner satisfaction rates with malleable (AMS 600-650) and two-piece inflatable penile prosthesis (Ambicor) in patients who underwent a penile prosthesis implantation due to erectile dysfunction.

Materials and methods

Following an approval from our institutional ethical board, the Medical Faculty of Uludag University and written consent from the patients involved, patients who underwent AMS 600-650 or Ambicor penile prosthesis implantation in a single tertiary referral center between January 2008 and January 2013 were included in the study. The type of penile prosthesis was chosen jointly by the patient and the clinician together. Patients who were not Turkish-speaking, who were deceased or whose prosthesis were explanted within 6 months following the surgery were excluded. Patient demographics and implant characteristics were recorded.

The modified Erectile Dysfunction Inventory of Treatment Satisfaction questionnaire (EDITS) was used to assess the satisfaction with the prostheses for erectile dysfunction and to investigate the impact of the patient and partner satisfaction on the treatment continuation. This questionnaire evaluates the overall patient satisfaction, the degree to which the prosthesis met patient expectations, the likelihood of continued use, the ease of use, the confidence in the ability to engage in sexual activity and the patient-reported partner satisfaction.

Statistical analysis

The statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) software version 20.0. The data are given as the means±standard deviation (SD). A t-test was used for comparisons between two groups with normal distribution. The categorical data are presented as numbers and percentages and were tested with a Chi-square test. Statistical significance was considered at the $p \leq 0.05$ level.

Results

A total of 72 patients had either AMS 600-650 or Ambicor penile prosthesis during the study period. Of the 68 patients who met our inclusion criteria, 46 patients who agreed to respond to the EDITS questionnaire were reviewed. The mean age of the patients was 56.7±12.9 and 58.6±9.5 in AMS 600-650 and AMS Ambicor group, respectively. There was no significant difference between the groups in terms of the patients' ages ($p=0.52$). The indications for the penile prosthesis AMS 600-650 were vascular dysfunction in 17, radical prostatectomy in 3 and priapism in 3 patients. In the AMS Ambicor group, the indications were vascular dysfunction in 18, chronic renal failure (the patient with renal transplant) in 1, and previous pelvic surgery in 4 patients.

Comparison of the EDITS score between the two groups is presented in Table 1. Overall satisfaction rates and the likelihood of continued use were significantly higher in the AMS Ambicor group ($p=0.013$ and $p=0.018$, respectively). Other answers from the EDITS revealed more patient satisfaction with Ambicor; however, this result was statistically insignificant.

Discussion

The results of the present study showed higher satisfaction rates with the two-piece inflatable prostheses when compared to malleable prostheses.

The percentages of patients who reported to be very satisfied with Ambicor and AMS 600-650 were 34.78% and 73.91, respectively. Natali et al.[9] reported 67% and 56% very satisfied patients with Ambicor and AMS 600-650, respectively. In this study, patient satisfaction with prostheses was investigated with the modified EDITS questionnaire (by Levine and colleagues). They did not report whether these patient satisfaction rates with the AMS Ambicor and AMS 600-650 were significantly different. We found that there was a statistically significant difference between the patient satisfaction rates with the AMS Ambicor and 600-650. Minervini and colleagues[10] reported 71% patient satisfaction with the AMS 600-650 by an interview made during office visit or telephone. They considered patients to be satisfied when the patients reported to be able to have satisfactory intercourse and were happy with the results of the operation. Chiva Robles et al.[11] reported acceptable satisfaction in 54% of the

Table 1. Results obtained using the modified Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) for AMS malleable and Ambicor penile prostheses

Questions	Answers	AMS malleable (%) (n=23)	AMS Ambicore (%) (n=23)	
Overall, how satisfied are you with your penile prosthesis?	Very satisfied	34.78	73.91	0.013*
	Neither satisfied nor dissatisfied	30.43	13.04	
	Very dissatisfied	34.78	13.04	
During the past four weeks, to what degree has the treatment you received for your erectile dysfunction met your expectations?	Completely	30.43	52.17	0.061
	Somewhat	34.78	34.78	
	Not at al	34.78	13.04	
How likely are you to continue using your penile prosthesis?	Very likely	30.43	65.21	0.018*
	Neither likely nor unlikely	34.78	21.73	
	Very unlikely	34.78	13.04	
During the past four weeks, how easy was it for you to use this treatment?	Very easy	39.13	69.56	0.056
	Neither easy nor difficult	26.08	13.04	
	Very difficult	34.78	17.39	
How confident has your penile prosthesis made you feel about your ability to engage in sexual activity?	Very confident	47.82	78.26	0.106
	It has had no impact	26.08	4.34	
	Considerably less confident	26.08	17.39	
Overall, how satisfied do you believe your partner is with the effects of this treatment for your erectile dysfunction?	Very satisfied	39.13	47.82	0.182
	Neither satisfied nor dissatisfied	26.08	39.13	
	Very dissatisfied	34.78	13.04	

AMS: American Medical Systems *p<0.05

patients with AMS 600-650 by telephone interview. Our results are in accordance with those previously reported.

Levine et al.[12] found 91% overall patient satisfaction rates with AMS Ambicor. In this study, they used the modified (by Levine et al) EDITS questionnaire with eight items, and each item categorized patients into five different subsets according to their satisfaction status. Lux et al.[13] reported 85% overall patient satisfaction with the AMS Ambicor by using a modified EDITS questionnaire with six items. They calculated the overall patient satisfaction by adding the number of patients who reported to be very satisfied to those somewhat satisfied. We used the modified EDITS questionnaire with six items, and each item classified patients into three subgroups according to their satisfaction rates, and patient satisfaction status with implants was categorized into three subclasses; very satisfied, neither satisfied nor dissatisfied and very dissatisfied. These patient satisfaction rates with the AMS Ambicor cannot be compared with those of the present study because only patients who reported to be very satisfied with their penile implants were accepted as satisfied.

Today, the three-piece inflatable prosthesis is the most preferred type of prosthesis. Carson et al.[14] evaluated the AMS 700CX prosthesis in 372 men and reported an overall satisfaction rate of more than 85% after a median follow-up of 47.7 months. Goldstein et al.[15] evaluated the Mentor three-piece inflatable prosthesis in 434 men and reported that expectations were realized in 89%. Additionally, they reported an overall satisfaction of over 80% after a mean follow-up of 22.2 months. These reported satisfaction rates with the three-piece prosthesis are higher than those with both the two-piece and malleable prostheses reported in the present study.

The patients with implanted AMS Ambicor were more likely (65%) to continue using their prostheses than those with AMS 600-650 (30). Natali et al.[9] reported that the likelihood of continued use by patients for the AMS Ambicor was 89% (n=59) and for the AMS 600-650 was 56% (n=9). In the study by Lux and colleagues[13], 75% of the patients with AMS Ambicor reported to be moderately or very likely to continue using their prostheses. These results are in line with our findings.

In our study, we did not find any differences between AMS Ambicor and AMS 600-650 in terms of ease of use, confidence in the ability to engage in sexual activity, or meeting of expectations of patient and patient-reported partner satisfaction. Lux et al.[13] reported 79% partner satisfaction rates with redesigned

Turkish Journal of Urology 2014; 40(4): 207-10
DOI:10.5152/tud.2014.37108

two-piece inflatable prosthesis. Levine et al.[12] evaluated 131 men who underwent two-piece inflatable prosthesis (Ambicor), and they reported 90% partner satisfaction rates. In our study, patient-reported satisfaction rates (very satisfied) with AMS 600-650 and Ambicor were 39.13% and 47.82%, respectively. Partner satisfaction rates with Ambicor reported by these authors previously are higher than those reported in the present study.

The current study has some limitations including a retrospective design, selection bias and small sample size. In our study, partner satisfaction is evaluated by the patients instead of the partners themselves. This could be another limitation. We believe a prospective multicenter studies with more patients will improve our understanding of comparing the satisfaction rates between these two implants.

In conclusion, the AMS Ambicor provides much more overall patient satisfaction than the AMS 600-650. The patients implanted with the AMS Ambicor are more likely to continue using their prostheses than those implanted with AMS 600-650. However, the AMS Ambicor has the same results as the AMS 600-650 in terms of the ease of use, confidence in the ability to engage in sexual activity, and meeting the expectations of the patient and those of the partner, as reported by the patient.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Uludağ University Faculty of Medicine.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - H.K.; Design - Y.K., H.K.; Supervision - H.K., Y.K., B.C.; Materials - Y.K., K.G.; Data collection and/or Processing - B.C., O.K.; Analysis and/or Interpretation -Y.K., H.K., B.C., K.G.; Literature Review - Y.K., K.G.; Writer - Y.K.; Critical Review - H.K., B.C.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

Etik Komite Onayı: Bu çalışma için etik komite onayı Uludağ Üniversitesi Tıp Fakültesi'nden alınmıştır.

Hasta Onamı: Yazılı hasta onamı bu çalışmaya katılan hastalardan alınmıştır.

Hakem değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir - H.K.; Tasarım - Y.K., H.K.; Denetleme - H.K., Y.K., B.C.; Malzemeler - Y.K., K.G.; Veri toplanması ve İşlenmesi - B.C., O.K.; Analiz ve /veya yorum -Y.K., H.K., B.C., K.G.; Literatür Taraması - Y.K., K.G.; Yazıyı yazan - Y.K.; Eleştirel İnceleme - H.K., B.C.

Çıkar Çatışması: Yazarlar çıkar çatışması bildirmemişlerdir.

Finansal Destek: Yazarlar bu çalışma için finansal destek almadıklarını beyan etmişlerdir.

References

1. Montague DK. Penile prosthesis implantation for end-stage erectile dysfunction after radical prostatectomy. Rev Urol 2005;7:51-7.
2. Mulcahy JJ, Austoni E, Brada JH, Ki Choi H, Hellstrom WJG, Krisnamurti S, et al. Implants, mechanical devices and vascular surgery for erectile dysfunction. In: Lue TF, Basson R, Rosen R, Giuliano F, Khoury S, Montorsi F, eds. Sexual medicine: Sexual dysfunctions in men and woman. Paris: Health publications; 2004:469-98.
3. Sadeghi-Nejad H. Penile prosthesis surgery: A review of prosthetic devices and associated complications. J Sex Med 2007;4:296-309.
4. Hatzimouratidis K, Eardley I, Giuliano F, Hatzichristou D, Moncada I, Salonia A, et al. Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation, 2014:24.
5. Nielsen KT, Bruskewitz RC. Semirigid and malleable rod penile prostheses. Urol Clin North Am 1989;16:13-23.
6. Chiang HS, Wu CC, Wen TC. 10 years experiences with penile prosthesis implantation in Taiwanese patients. J Urol 2000;163:476-80. [CrossRef]
7. Nickas ME, Kessler R, Kabalin JN. Longterm experience with controlled expansion cylinders in the AMS 700CX inflatable penile prosthesis and comparison with earlier versions of the Scott inflatable penile prosthesis. Urology 1994;44:400-3. [CrossRef]
8. Trost LW, Baum N, Hellstrom WJ. Managing the difficult penile prosthesis patient. J Sex Med 2013;4:893-906. [CrossRef]
9. Natalli A, Olianas R, Fisch M. Penile implantation in Europe: Successes and complications with 253 implants in Italy and Germany. J Sex Med 2008;5:1503-12. [CrossRef]
10. Minervini A, Ralph DJ, Pryor JP. Outcome of penile prosthesis for treating erectile dysfunction: Experience with 504 procedures. BJU Int 2006;97:129-33. [CrossRef]
11. Chiva Robles V, Lianes Gonzalez L, Pascal Mateo C, Espinales Castro G, Romero Cajigal I, Berenguer Sanchez A. Penile prosthesis. Quailty outcomes and morbidity. Arch Esp Urol 2005;58:925-30.
12. Levine LA, Estreda CR, Morgentaler A. Mechanical reliability and safety of, and patient satisfaction with Ambicore inflatable penile prosthesis: Results of a 2 centers study. J Urol 2001;166:932-7. [CrossRef]
13. Lux M, Reyes-Vallejo L, Levine LA. Outcomes and satisfaction rates for redesigned 2- piece penile prosthesis. J Urol 2007;177:262-6. [CrossRef]
14. Carson CC, Mulcahy JJ, Govier FE. Efficacy, safety and patient satisfaction outcomes of the AMS 700CX inflatable penile prosthesis: results of a long-term multicenter study. AMS700 CX Study Group. J Urol 2000;164:376-80. [CrossRef]
15. Goldstein I, Newman L, Baum N, Brooks M, Chaikin L, Goldberg K, et al. Safety and efficacy outcome of Mentor α-1 inflatable penile prosthesis implantation for impotence treatment. J Urol 1997;157:833-9. [CrossRef]