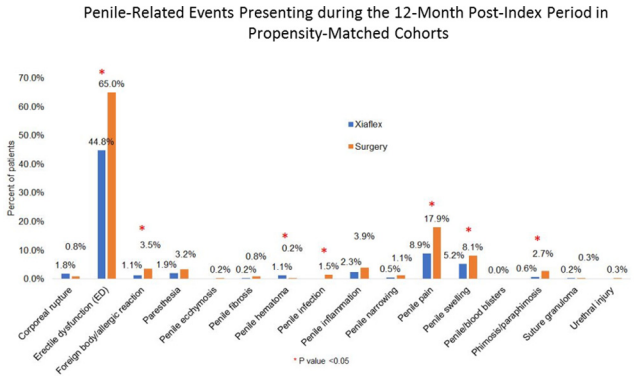
Methods: A retrospective analysis was performed using the IQVIA Real-World Data Adjudicated Claims Database, which includes records on >150 million individuals. Adult men newly diagnosed with PD were included if they received treatment with either collagenase or penile surgery (plication, incision/excision and grafting, and prosthesis) between January 1, 2014 and June 30, 2017. The first treatment date was the index date. Patients had continuous enrollment from ≥6 months before to 12 months after the index date. Patients in collagenase and surgery cohorts were matched on propensity score developed from baseline characteristics. Outcomes, including penile-related complications and concomitant medication use, were compared between the matched cohorts during the 12-month post-index period.

Results: A total of 1,847 men (1,227 for collagenase and 620 for surgery; mean age, 54-55 years) were identified. After propensity score matching, 620 patients remained in each cohort, which were similar in age, Charlson Comorbidity Index, history of erectile dysfunction (ED), PD duration, prior oral and intralesional PD therapies, pain medications, and ED therapies. The newly emerged post-procedural complication rate was higher in the surgical cohort compared to the collagenase cohort (25.3% *vs* 18.4%, P=0.003). Specifically, the surgery cohort had higher new event rates for penile pain (9.7% *vs* 5.3%, P=0.003), penile infection (1.3% *vs* 0, P=0.005), and phimosis/paraphimosis (2.1% *vs* 0.6%, P=0.029), but lower new event rates for penile hematoma (0.2% *vs* 1.1%, P=0.034) and corporeal rupture (0.3% *vs* 1.6%, P=0.021). The overall rate of re-occurring and newly developed complications was also higher in the surgery cohort compared to the collagenase cohort for ED (65.0% *vs* 44.8%, P<0.0001), foreign body allergy (3.5% *vs* 1.1%, P=0.005), and penile swelling (8.1% *vs* 5.2%, P=0.044), regardless of medical history (Figure). In addition, men who underwent surgery were more likely to fill an opioid (93.3% *vs* 38.9%, P<0.001) or NSAID (27.0% *vs* 20.3%, P=0.006) prescription and were more likely to be hospitalized for PD-related complications (2.9% *vs* 0.5%, P=0.002). Of those patients in the surgical cohort who filled an opioid prescription, 94.8% did so within the first post-procedural week. Although the ED rate was higher in the surgical cohort, a lower percentage of patients filled ED-related prescriptions (25.0% *vs* 31.9%, P=0.008) post-index date, possibly due to receipt of penile prosthesis during surgery.

Conclusions: Based on insurance claims data, surgery for PD was associated with a higher rate of penile-related complications compared to collagenase in the year following initial treatment. Surgery was also associated with a higher rate of hospitalization for PD-related complications and a greater need for opioids and NSAIDs.



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IMBALANCE IN PRESENTATION OF RISKS AND BENEFITS OF PENILE ENHANCEMENT PROCEDURES IN DIRECT-TO-PATIENT ONLINE MARKETING

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Introduction: Penile enhancement procedures stir controversy at the crossroads of aesthetic versus medically-necessary sexual medicine interventions. Multiple synthetic injections and surgical procedures are offered by a range of subspecialists and marketed directly to patients online. Web-based marketing is loosely regulated, at times with an imbalanced presentation of risks and benefits.

Objective: We analyzed web-based marketing of penile enhancement procedures and assessed the comparative disclosure of complimentary versus critical information.

Methods: We searched the internet using Google and the Google Trends tool for websites offering 'penile enhancement' procedures. We then compared page clicks a user would need in order to find advertised benefits of the offered procedure, in comparison to page clicks a user would need to find information critical of the procedure. Critical information included risks, complications or other disparaging information regarding an advertised procedure.

Results: We identified 34 unique sites offering injections or surgical procedures. These unique sites included 23 in the United States, and 11 outside the United States (Australia, Canada, England, France, South Korea). Subspecialists included 16 (47%) plastic surgeons, 12 (35%) urologists, 3 (9%) dermatologists and 3 (9%) other specialties. Synthetic injectable material included platelet rich plasma, hyaluronic acid, and polycaprolactone. Distinct procedures included dermal grafts, suspensory ligament release, and implant.

Figure 1 shows the distribution of our findings. Only 4 (12%) sites provided critical information in the same number of page clicks as complimentary information. 16 (47%) offered no critical information. The average number of page clicks to benefits was 0.4 (range 0-3) and the average number of page clicks to risks was 1.6 (range 0-3). Interventions offered in the United States were less likely to offer critical information in the same number of clicks as interventions offered outside the United States (4.3% vs 27.3%).

Conclusion: Direct-to-patient online marketing of penile enhancement procedures is offered by a range of sub-specialists. There is an objective imbalance in the discussion of benefits and risks of intervention, as measured by 'page-clicks'. Providers outside the United States provide critical information more readily than those within the United States.

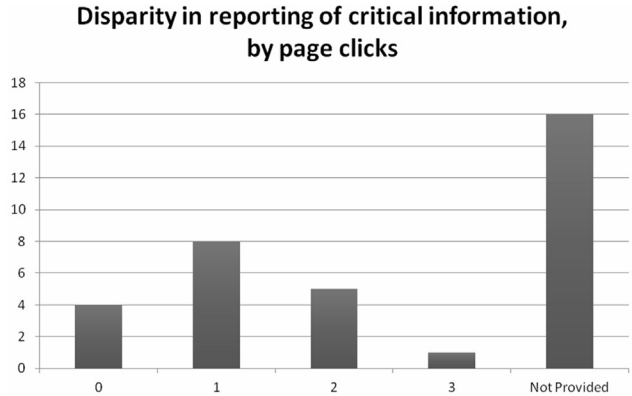

Figure 1.

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