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Male Sexual Dysfunction

Subcutaneous Placement of Inflatable Penile Prosthesis Reservoirs

Bruce B. Garber and Michael Bickell

OBJECTIVE
To review our experience with subcutaneous inflatable penile prosthesis reservoir insertion in a large, single-surgeon series.

MATERIALS AND METHODS
We carried out a retrospective review of 1000 consecutive Coloplast Titan inflatable penile implant procedures carried out by a single high-volume surgeon. Eight patients underwent subcutaneous reservoir placement (SRP) and are the subject of this review.

RESULTS
Eight of our last 1000 patients underwent SRP. SRP was only employed in patients with a thick subcutaneous abdominal fat layer, which would be capable of concealing the reservoir. Seven patients recovered uneventfully, and none reported a palpable or visible reservoir. One patient, who had 5 prior penile implant procedures, developed peri-prosthetic infection, and required complete device removal. Reservoir removal in this obese patient was facilitated by the device’s subcutaneous location.

CONCLUSION
SRP is a viable option for carefully selected obese patients. We suggest that this approach only be utilized in those with high body mass index and a thick subcutaneous abdominal fat layer. In thinner patients, the reservoir will be visible and/or palpable; we do not recommend subcutaneous placement under those circumstances.

Inflatable penile prostheses (IPPs) are a well-established treatment option for organic erectile dysfunction that does not respond to conservative measures. The traditional location for an IPP reservoir is the retropubic space of Retzius (SOR). This is typically accomplished via blind puncture through the floor of the inguinal canal, or under direct vision via a counter-incision or infrapubic approach. However, a variety of infrequent but severe complications have been reported with SOR reservoir placement, including bowel, bladder, vascular and ureteral injuries, and reservoir herniation. In response to this, there are a number of recent reports detailing alternate sites, methods, and results of reservoir placement within the abdominal wall, usually in the space anterior to the transversalis fascia and posterior to the rectus abdominis muscles. Abdominal wall reservoir placement techniques are gaining an increasing amount of traction among implanting urologists. However, these techniques can be difficult in obese patients.

Obesity and morbid obesity have become an epidemic in the United States. Recent data from the National Institute of Health indicate that 74% of U.S. men are overweight or obese, with a body mass index (BMI) of 25-39.9, and 4% have extreme obesity, with a BMI of ≥40. Consequently, implanting urologists are seeing an increasing number of overweight and obese men. Traditional SOR reservoir placement and high submuscular reservoir placement can be very difficult in this subset of patients, especially in the setting of prior abdominal surgery. We have employed subcutaneous reservoir placement (SRP) in some of these patients. Our literature review revealed only two prior case reports of subcutaneous penile implant reservoir placement. In this study, we present our series of obese patients who underwent SRP.

MATERIALS AND METHODS
We carried out a retrospective review of 1000 consecutive Coloplast Titan IPP procedures carried out by a single surgeon. Initial implants and revisions were included. Of these patients, 8 were selected for SRP, and are the subject of this review. Implantation was carried out using standard techniques, via a scrotal or infrapubic incision. The decision to carry out SRP was made intraoperatively. Criteria for SRP included: (1) a thick abdominal wall fat layer that would conceal the reservoir, and (2) difficulty or inability to safely carry out standard SOR or abdominal wall reservoir placement. When performing SRP via a scrotal incision, the reservoir was tunneled medially and the neck of the tunnel was approximated with absorbable suture, to avoid postoperative reservoir herniation. When performing SRP via an infrapubic incision, Scarpa’s and Camper’s fascias were approximated anterior to the reservoir, with 2-3 layers of running absorbable suture. A 125 cc Coloplast cloverleaf reservoir with a lockout valve was used in all cases. The reservoir was filled with

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the minimal amount of saline required for full cylinder inflation, as determined by a surrogate reservoir test. This technique allows the cloverleaf reservoir to lay relatively flat within the abdominal wall. A closed suction drain and Foley catheter were used in all cases, and removed on the first postoperative day. Patients were then seen at 2 weeks for a wound check, at 6 weeks for inflate-deflate teaching, and periodically thereafter.

RESULTS

Table 1 lists relevant information about these 8 patients. The average BMI in this series was 39, ranging from 28 to 49. All patients were available for postoperative follow-up, which ranged from 3 to 11 months. Seven of the 8 patients healed uneventfully. Postoperative exam revealed that none had a palpable or visible reservoir, no reservoir hernias developed, and all devices functioned normally. None of the 7 patients commented or complained about reservoir visibility or palpability. Figure 1 shows the postoperative result of patient #7.

Patient #4 developed peri-prosthetic infection and required explantation. This patient was a high-risk implant candidate who had 2 prior implants removed due to infection and was reimplemented despite scarred corpora. Reservoir removal in an infected, obese patient can be quite difficult; however, reservoir removal in patient #4 was quite easy due to its subcutaneous location.

CONCLUSION

With the high prevalence of obesity in the U.S., implanting surgeons can expect to see an increasing number of obese patients who request penile implant insertion. Obesity can significantly alter anatomic structures and relationships. SOR reservoir insertion in an obese patient, especially one with prior pelvic surgery, can be difficult, risky, or impossible. Over the last few years, in an attempt to avoid the well-known risks of SOR reservoir insertion, implanting urologists have increasing embraced abdominal wall reservoir insertion techniques. Reznicek et al recently published a thorough review of these techniques and their historical progression. Armed with sufficient published data, Coloplast Corporation was able to obtain formal Food and Drug Administration approval for ectopic insertion of the Coloplast cloverleaf reservoir in May of 2015.

Our literature review revealed only two prior case reports of SRP. In this manuscript we expand that literature, and present a small, preliminary series of SRP patients with short follow-up. Our results indicate that in carefully selected obese patients, SRP can be a safe and effective option. In addition, if an SRP patient ever requires implant removal or replacement, the reservoir will be easily accessible. We restrict SRP to those patients with a thick subcutaneous fat layer, which will conceal the reservoir. We do not recommend SRP for thin or mildly obese patients, as the reservoir will then be easily palpable and visible. We believe that our increased use of SRP in recent years has been due to an increased number of very obese patients who request an IPP, and to the increasing acceptance of ectopic reservoir insertion by implanting urologists. One caveat of the SRP technique is that if the patient subsequently loses a considerable amount of weight, he may require reservoir repositioning to a deeper location. It is also currently unknown whether a subcutaneous reservoir would be more prone to erosion, migration, or malfunction, by virtue of attachment to the abdominal wall. Therefore, long-term observation is necessary.

Table 1. Characteristics of patients who underwent subcutaneous reservoir placement

<table>
<thead>
<tr>
<th>Pt. Number</th>
<th>Age</th>
<th>Weight (lbs)</th>
<th>BMI</th>
<th>IPP surgical approach</th>
<th>Length of Follow-up (Months)</th>
<th>Previous Surgical Procedures</th>
<th>Postoperative Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>67</td>
<td>220</td>
<td>30</td>
<td>Scrotal</td>
<td>11</td>
<td>IPP implant (9/2013) and explant (11/2013)</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>64</td>
<td>295</td>
<td>44</td>
<td>Scrotal</td>
<td>9</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>4</td>
<td>73</td>
<td>260</td>
<td>35</td>
<td>Scrotal</td>
<td>3</td>
<td>5 prior IPP procedures, 2 prior infections</td>
<td>Infection requiring explant</td>
</tr>
<tr>
<td>5</td>
<td>70</td>
<td>210</td>
<td>28</td>
<td>Scrotal</td>
<td>8</td>
<td>Robotic prostatectomy 2014</td>
<td>None</td>
</tr>
<tr>
<td>6</td>
<td>68</td>
<td>292</td>
<td>47</td>
<td>Scrotal</td>
<td>8</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>7</td>
<td>61</td>
<td>352</td>
<td>49</td>
<td>Scrotal</td>
<td>7</td>
<td>IPP explant and reimplant × 3</td>
<td>None</td>
</tr>
<tr>
<td>8</td>
<td>54</td>
<td>279</td>
<td>38</td>
<td>Infrapubic</td>
<td>6</td>
<td>Umbilical hernia repair</td>
<td>None</td>
</tr>
</tbody>
</table>

BMI, body mass index; IPP, inflatable penile prosthesis.
its more superficial location. With short-term follow-up, SRP in carefully selected obese patients can be considered another option in the implanting urologist’s surgical armamentarium. More patients and longer follow-up will be required to see if these promising results will endure.

References

EDITORIAL COMMENT
“Ectopic” reservoir indicates that the reservoir is placed outside of the traditional retroperitoneal location during an inflatable penile prosthesis (IPP). Abdominal wall placement of the reservoir was first published 13 years ago. The technique followed commercial availability of reservoir equipped with a lockout valve that allowed placement of the reservoir in a location that was not an actual space and was therefore subject to muscular pressures. Reservoirs without this enhancement would have experienced undesirable auto inflation in submuscular spaces. The technique was also useful with the artificial urinary sphincter’s balloon. The technique for both devices involved pushing the component through the back wall of the inguinal canal with the finger into a submuscular location in the low abdominal wall. The technique never gained much traction because the device was frequently palpable in the groin and scrotal herniation occasionally occurred. When physicians began to use instruments like a long nasal speculum or a lung grasping forceps, placement of the reservoir in a higher submuscular abdominal wall location obviated those disadvantages.

It is my belief that the recent FDA authentication that the Coloplast Cloverleaf reservoir could be placed in a location outside of the space of Retzius gives us an opportunity to witness a paradigm shift in a surgical procedure that has been performed for over 40 years. No longer are we patients at risk for experiencing vessel or viscus injury during the implantation or removal of a reservoir. Nor do they need a secondary incision for safety’s sake. No longer are occasional implanters likely to offer IPP only to patients devoid of anatomic issues making traditional reservoir placement problematic, that is, hernia, pelvic surgery, pelvic radiation, obesity, etc.

The authors in this report confirm another variation of the same theme of substituting abdominal wall location for the retroperitoneal space of Retzius. Perceiving danger during reservoir placement utilizing previously described submuscular techniques in the morbidly obese, these authors basically say that if the patient has a large abdominal fat pad, the reservoir can be placed subcutaneously without it being subsequently visible or palpable to the examining hand.

It is my belief that widespread utilization of these new “ectopic” locations for the IPP and artificial urinary sphincter reservoirs will make physicians more likely to offer these quality of life enhancements to their patients. Many more patients need the devices than are receiving them presently. The number of devices implanted yearly should increase significantly by removing the dangers of the traditional location for the reservoir.

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AUTHOR REPLY
We would like to thank the reviewers for their thoughtful comments. On April 13, 2015, Coloplast Corp. received U.S. FDA approval for ectopic reservoir placement. This approval was based on FDA review of 9 published references. In our series, we have expanded the published literature on ectopic reservoirs, specifically involving subcutaneous reservoir placement (SRP). We used this technique on <1% of patients, specifically those with a thick subcutaneous fat layer, which would be capable of concealing the reservoir. However, we do not yet feel that ectopic placement should be considered a paradigm shift. There is a large amount of literature reporting on traditional space of Retzius (SOR) placement, and a much smaller amount concerning ectopic placement. Ectopic placement does not conceal the reservoir as well as SOR placement in thin individuals. We believe...
that more patients, more authors, and longer follow-up are required before we come to any final conclusions about these issues. We continue to prefer SOR reservoir placement in uncomplicated cases, and have published recommendations on how to avoid visceral injury. However, for those patients with anatomic issues (e.g., hernia repair with mesh, prior pelvic surgery, morbid obesity, etc.) we freely use ectopic placement. Ectopic sites we have safely used include the space immediately subjacent to: the rectus muscle, the anterior rectus fascia, the external oblique muscle, the external oblique fascia, and Scarpa’s fascia. Rather than considering ectopic placement as a paradigm shift, we prefer to consider these techniques as additional reservoir placement options that implanting urologists now have at their disposal.

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