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Transcatheter Arterial Embolization of Prostate in Hormone Induced Canine Prostate Hyperplasia
Transcatheter Arterial Embolization of Prostate in Hormone Induced Canine Prostate Hyperplasia

by

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A Dissertation Submitted to The Graduate School of Ajou University in Partial Fulfillment of the Requirements for the Degree of

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Transcatheter Arterial Embolization of Prostate in Hormone Induced Canine Prostate Hyperplasia

Purpose: Benign prostate hyperplasia (BPH) is the most common reason for surgical intervention among elderly men. Currently, main treatment modalities are medication and transurethral resection of the prostate (TURP) which is considered as the gold standard for the surgical management of symptomatic BPH. A number of minimally invasive techniques for treatment of BPH have increased significantly over the past 20 years. However, few new modalities have been presented so far, because of a limited results and some serious complications. There is a literature about transarterial prostate embolization is effective for the reduction in prostate volume and relief of urinary symptoms in a patient with BPH. The purposes of this study are to present the experiences of animal benign prostate hyperplasia model with combination therapy of hormones and to evaluate the efficacy and safety of transarterial prostate embolization for reduction of the volume in hormone induced canine prostate hyperplasia, prior to clinical application.

Materials and Methods: Nine castrated male beagle dogs were included. Prostate hyperplasia were induced by administration of dihydrotestosterone combined with β-estradiol in all dogs. In group A (n=4), the hormones were administered for 12 weeks. Two of them underwent transarterial embolization after hormone injections. Embolization was not performed in the remaining two. In groups B (n=5), the hormones were injected for 24 weeks.
Three of them underwent embolization 12 weeks after initiation of the hormone treatment and embolization was not performed in the remaining 2. Embolization was performed using polyvinyl alcohol (PVA) particles. The volume of each prostate was measured 3 times by MR imaging in all dogs, before the hormone treatment, and 12 weeks and, 24 weeks after hormonal administration. The dogs were sacrificed and the prostates were harvested after 3rd MR imaging. The prostates and bladders were evaluated grossly as well as microscopically.

**Results**: The mean volume of the prostates increased by 157.23±112.11% in the nine dogs after 12 weeks of hormone administration. In group A (n=4), 3rd MRI at 24th week showed decreased prostate volume of 68.55±0.15% in non-embolized dogs and 81.02±6.60% in embolized dogs compared to 12th week. In group B (n=5), the dogs that underwent embolization (n=3) showed increased prostate volume of 40.21±14.99% and non-embolization group (n=2) revealed increased prostate volume of 71.13±1.52% between 2nd and 3rd MRI. There was no gross and microscopic change in bladders except focal hemorrhage in one specimen. Under the microscope, pathologic findings of the prostate in dogs that underwent embolization showed cystic change with regenerative epithelium, fibrosis and inflammatory cell infiltration, unlike the non-embolized dogs.

**Conclusion**: Transcatheter arterial embolization is effective and safe to reduce the prostate volume without serious complications in hormone induced canine prostate hyperplasia.

Key Words : Prostate, Hyperplasia, Embolization
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I. INTRODUCTION

Benign prostate hyperplasia (BPH) is the most common human neoplasm, affecting 40-70% of men over 60 years and it is the most common reason for surgical intervention among elderly men (Glynn et al., 1985; Girman, 1998). Various medications such as α-blockers and 5α-reductase inhibitors for treatment of prostatic growth and lower urinary tract symptoms have been considered and that resulted in decrease of surgical treatment (Issa & Regan, 2007). However, still significant number of patients underwent surgical management. Currently, transurethral resection of the prostate (TURP) is considered as the gold standard for the surgical management of symptomatic BPH. Although complications have been significantly reduced with the development of newer technologies, TURP still have some limitations. It cannot be performed for the patients who are poor surgical candidates and have high risk of anesthesia. And it has also surgical morbidity and mortality. A number of minimally invasive techniques for treatment of BPH have increased significantly over the past 20 years. Prostatic tissue ablation with ethanol or thermal therapy, various laser therapies and intraurethral stents are the examples (Plante et al., 2003; Aho & Gilling, 2003; Klingler, 2003; Ogiste et al., 2003; Gravas et al., 2003; Plante et al., 2004; Stovsky et al., 2006). However, few new modalities have been presented so far, because of a limited results and some serious complications. Prostate embolization has been used in patients with bleeding after prostatic biopsy, transurethral prostatectomy or pelvic urological malignancies and successful results were reported (Appleton et al., 1988; Michel et al., 2002; Nabi et al., 2003). There is a reported case study about transarterial prostate embolization using polyvinyl
alcohol (PVA) is effective for the reduction in prostate volume and relief of urinary symptoms in a patient with BPH (DeMeritt et al, 2000). Transarterial PVA embolization of symptomatic BPH is minimally invasive, does not require general anesthesia, and appears to be effective modality not only bleeding control but also relief of voiding difficulties. As suggested by DeMeritt et al, analogous to uterine artery embolization for symptomatic fibroids, transcatheter arterial embolization of prostate may be an alternative treatment for symptomatic BPH (DeMeritt et al, 2000). Darewicz et al reported animal research related to prostatic embolization using histoacryl glue (Darewicz et al, 1980). But, it was not performed with BPH model and there was no comment about change of prostate size and surrounding organs. According to the published reports, BPH can be induced in dogs with hormone administration after castration (Gloyna et al, 1970; Walsh & Wilson, 1976; DeKlerk et al, 1979) and it is possible that prostate embolization with PVA particles can be performed in BPH model of dogs.

The purposes of this study are to present the experiences of animal benign prostate hyperplasia model with combination therapy of hormones and to evaluate the efficacy and safety of transarterial prostate embolization for reduction of the volume in hormone induced canine prostate hyperplasia, prior to clinical application.
II. MATERIALS AND METHODS

This protocol was approved by the Institutional Animal Care and Use Committee of our institution.

Nine male beagle dogs (age range; 11-18 months, weight range; 11.5-17 kg) were included.

A. Induction of the prostate hyperplasia

Castration was done by an urologist. Antibiotics for dogs was injected for 3 days. After 4 weeks for involution, 25 mg of dihydrotestosterone (5α-androstan-17β-ol-3-one, Sigma, USA) combined with 0.25 mg of β-estradiol (Sigma, USA) were injected in all dogs, three times a week. Hormones were suspended or dissolved with 1 ml of triolein and then injected subcutaneously over the dorsal, posterior cervical region.

In group A (n=4), the hormones were administered for 12 weeks. Two of them underwent Transcatheter arterial embolization after hormone injections. Embolization was not performed in the remaining two. In groups B (n=5), the hormones were injected for 24 weeks. Three of them underwent embolization 12 weeks after initiation of the hormone treatment and embolization was not performed in the remaining 2.

B. Magnetic resonance imaging

Beagles were sedated by intramuscular injection of sedatives (ketamine 10 mg/kg, xylozine 3.45 mg/Kg, atropine 0.04 mg/kg). Prostate images were obtained by 1.5 tesla MRI
system (Signa; GE medical system, Milwaukee, WI).

Following are the imaging protocols

Location 3 plane/location sagittal

Axial T2 weighted FSE (12 or 16cm FOV, 5mm thickness, 256x224 matrix)

Axial T1 weighted SE (12 or 16cm FOV, 5mm thickness, 256x224 matrix)

The volume of each prostate was measured 3 times by MRI in all dogs, before the hormone treatment, and 12 weeks and, 24 weeks after hormone administration. Volume measurement was performed by a radiologist in PACS system (PiViewSTAR: Infinitt, Seoul, Korea). In T1 weighted images, outline of prostate was drawn and area of drawing image was calculated automatically in PACS system.

Volume (ml) = Sum of areas at each image x slice thickness

C. Embolization

Anesthesia was done using the same method as for the MRI. Half dose of drug was injected during the procedure, if needed. Venous access was made in anterior leg using 24G needle and normal saline was dropped continuously.

Right or left inguinal area was prepared for angiography. Common femoral artery was surgically dissected by a vascular surgeon. A 5-Fr. sheath (Radiofocus introducer II: Terumo, Tokyo, Japan) was inserted through the right or left common femoral artery and pelvic angiography was done using a 5-Fr angiographic catheter (Tempo; Cordis, FL, U.S.A). After angiography of pelvis and both internal iliac arteries, supplying arteries to prostate
were selected using a microcatheter (Renegade; Boston scientific, MA, U.S.A). After identification of supplying arteries to the prostate, embolization was performed using 250-355 micrometer PVA particles (Contour; Boston scientific, MA, U.S.A). Embolization was ended when stasis of the flow was achieved. Procedure was completed after performing follow up angiography and sealing off the cut down site.

D. Pathologic findings

The dogs were sacrificed and the prostates were harvested within 48 hours after 3rd MR imaging. The prostates and bladders were evaluated grossly as well as microscopically by a pathologist.
III. RESULTS

A. Angiographic findings

Angiography of both internal iliac arteries showed contrast staining of prostate consistent with BPH. All of the supplying arteries were inferior vesical arteries, which were hypertrophied. In all dogs underwent embolization, all inferior vesical arteries successfully selected, except one. In one dog (No.1), branch of the prostate and bladder did not separated. To protect the cystic branch, it was selected with microcatheter and embolization was done using microcoils (Tornado; Cook, bloomingston, U.S.A). PVA particles were then injected through the inferior vesical artery to the prostate (fig.1). Four prostates were supplied equally from both inferior vesical arteries. In one dog (No.8), right inferior vesical artery supplied most of prostate and left inferior vesical artery supplied small part of left prostate. All dogs tolerated the whole procedure well and no immediate complication was noted.

a. b. c.
d. e.

Fig. 1. Embolization procedure. (a) Pelvic angiography shows contrast blush of the prostate, consistent with BPH. (b) Selective angiography of right inferior vesical artery shows contrast staining of right side prostate gland. (c) Selective angiography of left inferior vesical artery shows contrast staining of left prostate and branch to the bladder. (d) To protect the bladder supplying branch, coil embolization was done and prostate embolization using polyvinyl alcohol (PVA) was performed. (e) Post-procedural angiography shows no residual contrast staining of the prostate.
B. MRI findings and prostate volume change

The mean volume of the prostates increased by 157.23±112.11% in nine dogs after 12 weeks of hormone administration (table 1). Prostate hyperplasia obtained in all dogs at 12th week MRI except one. Last one dog eventually met the criteria of hyperplasia in 24th week.

In group A (n=4), 3rd MRI after 12 weeks of cessation of the hormones showed decreased prostate volume of 68.55±0.15% in non-embolized dogs and 81.02±6.60% in embolized dogs compared to the 2nd MRI. After cessation of the hormone injection, prostate volume decreased in both embolized and non-embolized dogs (fig.2). For preservation of hormone level and discrimination of embolization effect, hormones were continuously injected until the 24 weeks in group B. In group B (n=5), the dogs that underwent embolization (n=3) showed increased prostate volume of 40.21±14.99% and non-embolization group (n=2) revealed increased prostate volume of 71.13±1.52% between 2nd and 3rd MRI. Two of three dogs which underwent embolization demonstrated large cystic lesion within the prostate (fig.3). But, statistical significance cannot be calculated because of small sample size.

**Table 1. Characteristics of dogs and volume change of prostate.**

<table>
<thead>
<tr>
<th>Group</th>
<th>No.</th>
<th>BWt (kg)</th>
<th>Intervention</th>
<th>Treatment</th>
<th>Volume of prostate (ml)</th>
<th>Prostate volume change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initial</td>
<td>12 wks</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>12.5</td>
<td>embolization</td>
<td>dihydrotestosterone plus estradiol</td>
<td>10.00</td>
<td>21.53</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>15.5</td>
<td>embolization</td>
<td>dihydrotestosterone plus estradiol</td>
<td>4.33</td>
<td>16.62</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>11.5</td>
<td>none</td>
<td>dihydrotestosterone plus estradiol</td>
<td>7.00</td>
<td>15.38</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>14.5</td>
<td>none</td>
<td>dihydrotestosterone plus estradiol</td>
<td>7.57</td>
<td>14.42</td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>17</td>
<td>none</td>
<td>dihydrotestosterone plus estradiol</td>
<td>13.64</td>
<td>24.65</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>14</td>
<td>none</td>
<td>dihydrotestosterone plus estradiol</td>
<td>11.21</td>
<td>23.34</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>14</td>
<td>embolization</td>
<td>dihydrotestosterone plus estradiol</td>
<td>11.45</td>
<td>22.73</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>12</td>
<td>embolization</td>
<td>dihydrotestosterone plus estradiol</td>
<td>5.61</td>
<td>28.51</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>12</td>
<td>embolization</td>
<td>dihydrotestosterone plus estradiol</td>
<td>4.75</td>
<td>9.98</td>
</tr>
</tbody>
</table>

Hormone treatment was performed each canine in group A for 12 weeks and in group B for 24 weeks.
Fig. 2. T2 weighted MR images of dogs with embolization (upper row) and without embolization (bottom row) in group A. All three images were obtained at before hormone treatment, 12 weeks after hormone injection and before embolization, and 12 weeks after embolization. Last images show decreased size of prostate in both dogs without significant difference irrespective of embolization.
Fig. 3. T2 weighted MR images of dogs with embolization (upper row) and without embolization (bottom row) in group B. All three images were obtained immediately before hormone treatment, 12 weeks after hormone injection and 24 weeks from initial images. Serial images revealed continuous enlargement of the prostates. There are large cystic portions of prostate in embolized dog (arrow).
C. Pathologic findings

In group B, weights of all prostates of five dogs revealed more than 15gm, consistent with prostate hyperplasia in dogs.

Macroscopic examination of the sections of the prostate glands removed from the animals revealed large cystic portions in the prostate in two dogs that underwent embolization, consistent with the MRI findings. Under the microscope, prostates in dogs that underwent embolization showed cystic changes lined with regenerative epithelium and atrophied glands admixed with islands of normal glandular hyperplasia. Multifocal fibrosis with inflammatory cell infiltration and embolic material contained vessels were also revealed. All these findings were presented in peripheral gland, mainly. In prostates of non-embolized dogs, main findings were diffuse glandular hyperplasia with microcyst formation. One specimen of dog without embolization showed focal hemorrhage.

There was no gross and microscopic change in bladders except focal hemorrhage in one specimen without involvement of whole layer of bladder. But, even in this case, there was no voiding difficulty or hematuria. There was no gross damage in surrounding organ when examined during harvesting the prostates and bladders.
Fig. 4. Gross specimens of the prostate from group B. Left prostate from dog with embolization and right from dog without embolization. Both enlarged prostates reveal consistent with prostate hyperplasia and large cystic portion in prostate of embolized dog (left).
Fig. 5. Microscopic findings of prostate of dog with embolization. (a) Prostate specimen shows large cystic change (arrow) and diffuse atrophied glands with fibrosis. Normal glandular structures are seen in peripheral portion (broken arrow) (H&E stain, 1:1). (b) Low power field view of (a) (square of figure a). Island of gland within fibrosis and occluded vessel by embolization (arrow) are seen. (c) High power field view of figure (b) (square of figure b, x200). Diffuse infiltration of inflammatory cell.

Fig. 6. Microscopic findings of prostate of dog without embolization. Prostate specimen shows diffuse glandular hyperplasia with microcysts formation. (H&E stain. 1:1 left, x40 right).
Fig. 7. Gross specimen of bladder from dog with embolization. The specimen shows focal hemorrhagic change of bladder wall (arrow).
IV. DISCUSSION

As previously mentioned, BPH is the most common human neoplasm and the most common reason for surgical intervention among elderly men (Glynn et al, 1985; Girman, 1998). In surgical management, open prostatectomy is still frequently used (Gratzke et al, 2007), but transurethral prostatectomy is currently known as gold standard. Postoperative complications and surgical morbidity and mortality has been decreased with technological development, however they still remained important problem.

To solve these problems and to patients with unsuitable for operation, various minimally invasive treatment modalities emerged (Plante et al, 2003; Aho & Gilling, 2003; Klingler, 2003; Ogiste et al, 2003; Gravas et al, 2003; Plante et al, 2004; Stovsky et al, 2006). Among these, laser therapy is relatively well known method. However, most of laser therapies are required general or spinal anesthesia and catheterization is needed because of lack of immediate removal of prostatic tissues (Aho & Gilling, 2003). And laser equipment is not available everywhere. Other modality, another well known, intraprostatic injection also has limitations which are inconsistent method and cause serious complication such as extraprostatic necrosis (Plante et al, 2003). In aspect of clinical outcomes and cost effectiveness, many of these minimally invasive therapies does not show the superior results than the TURP (Stovsky, 2006).

There are some reports about the effectiveness of transcatheter arterial embolization to the bleeding control after prostatectomy or biopsy and pelvic malignancies (Appleton et al, 1988; Michel et al, 2002; Nabi et al, 2003). DeMeritt et al reported that transarterial prostate
embolization was effective not only bleeding control but also relief of BPH-related bladder outlet obstruction (DeMeritt et al, 2000). In our study, in group B that hormones were injected for 24 weeks, embolization could not prevent the further enlargement of the prostate. However, overall increased volume of prostate of embolized dogs was small compared with non-embolized dogs. We used the 250-355μm of PVA and that is larger than DeMeritt et al used. We thought that small size of PVA could cause the possibility of bladder infarction. However in most cases, embolization effects on prostate were found in peripheral gland. Maybe we could get the better results of embolization if we used the small size PVA.

Several complications secondary to internal iliac artery embolization were reported such as gluteal pain, neurological deficits and bladder necrosis (Carmignani et al, 1980; Appleton et al, 1988; Sieber, 1994). Neurological deficits didn’t suspected in all dogs after embolization. We also evaluated the bladder with prostate grossly and microscopically. There was a complication of focal bladder hemorrhage in one dog, however even in this case, hemorrhage did not involve the entire layer of bladder wall. And no other serious complication was found.

In group B, prostate hyperplasia was made in all dogs in pathologically. Microscopic findings of prostate of non-embolized dogs showed diffuse gland hyperplasia and microcyst formation. This finding is concurrent results with previous report (Walsh & Wilson, 1976).

Histologically, gland atrophy, fibrosis and inflammatory cell infiltration in prostate of embolized dogs were noted in our study. Similar findings of lymphocytes and fibroblasts infiltrations in interstitial tissue after embolization of the internal iliac arteries was reported in other study, they comment that this may be the result of reaction of the organ to ischemia.
(Darewicz et al, 1980). Zvara et al reported fibrosis and shrinkage of tissue is what most presumed to be the mechanism in relieving obstructive symptoms (Zvara et al, 1999). Their report was about the intraprostatic injection, however in correlation with their results, we thought that our histologic findings are also meaningful. Another notable pathologic finding of our study is large cyst formation in prostate of embolized dogs. There was no report about this finding after embolization, in our knowledge. We presumed that these large cysts resulted from ischemic necrosis and re-epithelialization was formed during the next 12 weeks. But we couldn’t find the reason of eccentric location of these cysts.

Usually, animal study for prostate hyperplasia is performed with dogs. Successful results of hormone induced canine prostate hyperplasia has been reported during several decades (Gloyna et al, 1970; Walsh & Wilson, 1976; DeKlerk et al, 1979). According to these reports, experimentally induced canine prostate hyperplasia was histologically indistinguishable from the spontaneous disease (DeKlerk et al, 1979).

Following known methods, we successfully made the prostate hyperplasia in dogs. But, most of reports were focused on hormonal effect to the development of prostate hyperplasia. We could not find the reports about the change of prostate after cessation of the hormones. Therefore, to discriminate the effects by hormone and embolization, we divided the dogs into the two groups. Prostate size decreased after cessation of hormone injection in group A regardless of embolization or not. Therefore, when evaluating of the effect of treatment after hormone injection of prostate hyperplasia, administration of hormones should be kept until the end of the study.

There are several limitations in our study. First, symptoms of outflow obstruction in
BPH caused by fibrostromal proliferation of the periurethral glands with subsequent encroachment on the urethra in human. However, in contrast to that in man, the enlarging gland rarely causes urinary tract obstruction (Krawiec & Heflin, 1992; Broderick et al, 1994). Therefore our results cannot show the effect on the BPH-related bladder outlet obstruction. For evaluating the more accurate effect to the BPH, direction of prostate growth should be controlled using other method (Broderick et al, 1994). Second, despite of our results that showing trend of less increased volume of prostate in embolized dogs, statistical significance could not be calculated because of the small sample size.
V. CONCLUSION

Transcatheter arterial embolization is effective and safe to reduce the prostate volume without serious complications in hormone induced canine prostate hyperplasia.
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국문요약

호르몬 유도하에 만들어진 개의 전립선 비대증 모델에서의 경동맥 색전술

연구목적: 전립선 비대증은 나이든 남자들에서 매우 흔한 질환이며, 수술적 치료를 요구하는 가장 흔한 질환이다. 현재 증상이 있는 전립선 비대증이 있는 환자에서 약물 치료와 수술적 방법으로는 경도의 전립선 질종치업이 가장 널리 쓰이고 있다. 최근 20 년간 전립선 비대증의 치료에 있어서 덜 침습적인 많은 방법들이 보고 되어 왔다. 그러나 만족스럽지 못한 결과들이 보고되었고, 간혹 심각한 합병증 역시 보고되어 현재는 그 중 몇 가지의 방법만이 일부에서 사용되고 있다. 전립선 비대증에 의한 증상과 헤뇨가 있었던 환자에서 경동맥 전립선 색전술이 전립선의 크기를 줄이고 증상을 호전시키는 효과가 있다는 보고가 있었다. 이에 저자들은 호르몬 유도하에 개의 전립선 비대증 모델은 만들어 경동맥 색전술을 시행한 후 전립선의 변화와 주변 장기의 변화를 관찰해 보고자 하였다.
연구대상 및 방법: 아홉 마리의 개가 본 연구에 포함되었다. 전립선 비대증은 dihydrotestosterone 과 β-estradiol 을 주입하여 만들어졌다. 그룹 A (n=4)는 12 주 동안 호르몬 치료를 하였으며, 그 중 2 마리는 12 주 후 PVA 를 이용하여 색전술을 시행받았다. 그룹 B (n=5)는 24 주 동안 호르몬을 주입하였으며, 그 중 3 마리에서만 12 주제 색전술을 시행하였다. 아홉 마리 모두에서 호르몬 주입전과 12, 24 주제 각각 자기공명영상 시행 후 정성적, 각각의 전립선 크기를 측정하였다. 3 번째 자기공명영상 시행 후 회생시켜 각각의 전립선과 방광의 육안적 소견과 현미경적 소견을 얻었다.

결과: 아홉 마리에서 호르몬 주입 후 12 주 제 전립선 크기 증가의 평균값은 157.23±112.11%였다. 그룹 A 에서 호르몬 중단 후 12 주 제 시행한 3 번째 자기공명영상에서 색전술을 시행받지 않은 2 마리는 평균 68.55±0.15%의 크기 감소를 보였으나 색전술을 시행받은 2 마리는 평균 81.02±6.60%의 크기 감소를 보였다. 그룹 B 에서는 12 주제와 비교해 24 주제의 전립선 크기는 색전술 시행받은 3 마리는 40.21±14.99%가 증가하였으나, 시행받지 않은 2 마리는 71.13±1.52%의 크기 증가를 보였다. 한 마리에서 조직 검사상 방광에 국소적인 출혈 소견이 있었던 것을 제외한 다른 합병증의 소견은 없었다. 현미경 소견상 색전술을 시행받은 개에서 얻어진 전립선은 재생 상피를 가진 남성 변화와, 섬유화, 염증 세포의 침윤을 보였다.

결론: 호르몬 유도하에 만들어진 개의 전립선 비대증 모델에서의 경동맥 색전술은 전립선의 크기 감소에 있어 효과적이며, 심각한 합병증을 초래하지 않는 안전한 방법이다.

핵심어: 전립선 비대증, 색전술