Chapter 6

ALTA Sclerotherapy: The New Sclerotherapy for Curing Advanced Internal Hemorrhoids

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Abstract

 Aluminum potassium sulfate and tannic acid (ALTA) sclerotherapy is a four-step direct injection sclerosing procedure, intended to shrink and harden internal hemorrhoids to eliminate hemorrhoidal prolapse and bleeding. ALTA sclerotherapy for internal hemorrhoids has been performed in over three hundred thousand (300,000) cases in Japan since the year 2000. In 2012 we reported a new treatment for internal hemorrhoids [1] and in 2013 reported that the blood flow in the hemorrhoidal tissue significantly decreased after ALTA sclerotherapy using trans-anal ultra-sonography [2].

ALTA sclerotherapy is a highly effective and low invasive treatment for internal hemorrhoids. Regarding symptoms associated with internal hemorrhoids, at one (1) month and one (1) year after ALTA sclerotherapy prolapse resolution in the cases studied was 100% and 87.9% respectively and bleeding was resolved in 100% and 80.0% of cases respectively. Patient satisfaction at the point of one (1) year after ALTA sclerotherapy was 97.7%.

The symptom score on a questionnaire completed by patients significantly decreased after ALTA sclerotherapy. The symptom scores (mean±S.D) at the pre-operative day, 1 post-operative month (POM), 3 POM, 6 POM and 12 POM were 14±4, 2±3, 2±4, 3±1 and 1±1, respectively. There was very little post-operative pain reported. The visual analogue scores (VAS) of pain (mean±S.D) at 1 post-operative day (POD), 8 POD, 15 POD and 29 POD were 1.3±1.7, 1.1±1.3, 1.3±1.5 and 0.7±1.3, respectively. There were

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nine (9) post-operative complications. All cases improved through conservative treatment.

The effectiveness of ALTA sclerotherapy, which shrinks and hardens internal hemorrhoids, is permanent. The blood flow in the hemorrhoidal tissue (power Doppler imaging area (PDI-area)), measured by trans-anal ultra-sonography, significantly decreased after ALTA sclerotherapy. The PDI-area (mean±S.D) at the pre-operative day, 1 POM and 12 POM were 0.46±0.50 cm², 0.07±0.06 cm² and 0.02±0.02 cm², respectively. The beneficial effect of this treatment continued over one (1) year.

ALTA sclerotherapy might also be a cure for Goligher grade 3 hemorrhoids as it is for Goligher grade 2 hemorrhoids. There was no significance observed in the cumulative recurrence rate between Goligher grade 2 and 3 hemorrhoids.

In conclusion, ALTA sclerotherapy could be a minimally invasive and curable treatment for advanced internal hemorrhoids.

Keywords and Acronyms: Aluminum potassium sulfate and tannic acid (ALTA); post-operative month (POM); visual analogue score (VAS); post-operative day (POD); power Doppler imaging (PDI); trans-anal ultra-sonography; procedure for prolapse and hemorrhoids (PPH); trans-anal hemorrhoidal dearterialisation (THD); anorectal junction junction (ARJ); power Doppler imaging area (PDI-area)

Introduction

Hemorrhoids are the most common anorectal disease. When hemorrhoidal tissue gives rise to symptoms such as bleeding, prolapse, or pruritus, one can employ the term “hemorrhoidal disease” [3]. Etiologic factors are multi-factorial and include prolonged straining, irregular bowel habits and heredity. Supporting connective tissue degenerates and hemorrhoidal cushions slide as a consequence.

Surgery is superior to drug treatment in terms of complete cure, but the candidates are frequently reluctant to undergo hemorrhoidectomy because of a relatively long hospital stay, time-consuming post-operative treatment, and excessive fear of post-operative pain and other complications [4]. Doctors and patients are expecting less invasive modalities which allow shorter hospital stay with an efficacy similar to that of surgery. The procedure for prolapse and hemorrhoids (PPH) is a technique that was based on the stapled trans-anal mucosectomy [5, 6].

The PPH is reported to be an effective and safe alternative for surgical hemorrhoidectomy with less post-operative pain, shorter hospital stay and greater patient satisfaction [7]. However, incidental but serious complications have been described8-11. Trans-anal hemorrhoidal dearterialisation (THD) reported low complication rates, minimal post-operative pain and overall good results. By arterial ligation the inflow is reduced, causing the plexus to diminish and the hemorrhoids to shrink [3, 12-14].

Aluminum potassium sulfate and tannic acid (ALTA) which was modified from a Chinese agent Xiaozhiling used for the treatment of internal hemorrhoids is injected into the hemorrhoids [4, 15]. After that, ALTA is used to reduce the inflow and induce persistent fibrosis, and promote the adhesion and fixation of mucosal and submucosal layers to the muscular layer, leading to non-invasive sclerosis and involution of the hemorrhoid [4, 16]. It was reported that ALTA sclerosing therapy was effective for prolapse and other symptoms of
ALTA Sclerotherapy

internal hemorrhoids [4]. ALTA was safe, and no serious adverse reactions occurred to patients included in the various studies cited. In Japan, ALTA sclerotherapy is recognized the same as several methods of surgical treatment for hemorrhoids.

Although conservative treatments such as those based on dietary and lifestyle changes and rubber band ligation can help the majority of patients, sclerotherapy and phlebotonic drugs can effectively treat grade 1 and grade 2 hemorrhoids, while surgery is required for the most advanced stages. Conventional hemorrhoidectomy is considered to be the gold-standard approach for grade 4 hemorrhoids [17].

The management of grade 3 hemorrhoids is controversial. An increasing number of minimally invasive treatment options, including mucopexy with or without mucosal resection and hemorrhoid artery ligation, have now been proposed for the management of grade 3 haemorrhoids. These approaches aim to correct the underlying patho-physiological mechanisms involved in the etiology of hemorrhoids. An increased risk of recurrence is the price to pay for these minimally invasive and less painful treatments, but the sparing of the sensitive anoderm and a rapid return to normal life without pain are greatly appreciated by patients [18].

This review showed ALTA sclerotherapy was introduced as the treatment for grade 1 or grade 2 hemorrhoids. However, ALTA sclerotherapy has been frequently performed for all grades of internal hemorrhoids as a minimally invasive treatment in Japan since 2000 [1, 4, 19-20]. Nowadays, ALTA sclerotherapy for internal hemorrhoids has been performed in over three hundred thousand (300,000) cases in Japan since the year 2000.

In the following sections, we present the effective results of ALTA sclerotherapy for advanced internal hemorrhoids.

The Action Mechanism of ALTA

ALTA compounds with aluminum potassium sulfate and tannic acid, and is made in the Mitsubishi Tanabe Pharma Corporation, Osaka, Japan. The aluminum ion induces a strong local inflammatory reaction, resulting in fibrosis [13, 14]. Tannic acid has a strong astringent effect on tissue, promoting protein coagulation and the contraction of blood vessels, while reducing exudation into tissues from the inflammatory reaction [13, 14].

These actions tend to prevent tissue necrosis, and promote sclerosis, adhesion of hemorrhoidal tissue and immediate hemostasis. It is effective for the prolapse and bleeding of internal hemorrhoids early after injection, with disappearance rates similar to those after surgery.

Indication for ALTA Sclerotherapy

ALTA sclerotherapy is effective for internal hemorrhoids. However, the following patients were excluded: patients with associated acute inflammatory internal hemorrhoids and acute irreducible hemorrhoids; patients with serious cardiac, hepatic, renal, and hematological diseases; pregnant women or women who may be pregnant; nursing mothers; and patients with a past history of hypersensitivity to local anesthetics.
Technique and Procedure of ALTA Sclerotherapy

Patients assumed the lithotomy position. Procedures were undertaken under local anesthesia, using the Z-type proctoscope (ARAKAWA SEISAKUJO, Tokyo, Japan) with a distally opening window that allowed for the application of an injection into the rectal mucosa. In each case, we first found a branch of the superior rectal artery through palpation or Doppler sound of arterial pulsation using Surgical Doppler II (MURANAKA IRYOUKI, Tokyo, Japan) as the Doppler blood flow meter. Second, we performed an ALTA four-step injection procedure as follows:

1. Injection of 3ml of ALTA into the sub-mucosa of the superior pole of the hemorrhoid. The syringe needle was inserted into the superior part of the hemorrhoid around the pulsating superior rectal artery.
2. Injection of 2-4ml of ALTA into the sub-mucosa in the central part of the hemorrhoid. The syringe needle was inserted into the central part of the primary hemorrhoid, and the dosing solution was injected deep into the sub-mucosa. The standard dose was the volume of the hemorrhoid plus 1 ml.
3. Injection of 1-2ml of ALTA into the mucous lamina propria in the central part of hemorrhoid. After injection into the sub-mucosa in the central part of the hemorrhoid, the needle tip was slightly pulled and 1-2ml of the dosing solution was injected into the mucous lamina propria.
4. Injection of 3-4ml of ALTA into the sub-mucosa at the inferior pole of hemorrhoid. The syringe needle was inserted at the inferior pole of the primary hemorrhoid (0.1-0.2cm above the dentate line), and 2-3ml of the dosing solution was injected deep into the sub-mucosa. Another 1ml was injected while pulling out the tip of the syringe needle (Figure 1).

Figure 1. Injection sites of procedure for four-step injection of ALTA. ALTA is injected four times into the primary haemorrhoid, divided into four parts including superior (around the pulsating SRA), central deep and superficial and inferior lying above the dentate line: (1) Sub mucosa of the upper end of hemorrhoid. (2) Sub mucosa at the center of hemorrhoid. (3) Lamina propria at the center of hemorrhoid. (4) Sub mucosa of lower end of hemorrhoid.
Assessment and Postoperative Follow-up

Patients were discharged with oral analgesia (acetaminophen) at three (3) days. They were followed up at one (1) day, one (1) week, two (2) weeks, one (1) month and one (1) year after the ALTA sclerosing therapy. Follow-up consisted of (1) a symptom questionnaire; (2) physical examination and anoscopic findings; and (3) trans-anal ultrasonography.

Symptom Questionnaire

The degree of severity of hemorrhoidal symptoms was scored for each patient using a specifically designed questionnaire assessing five (5) different parameters, each scoring 0 to 4 with 0 corresponding to no symptoms at all and 4 to the presence of the symptoms on a daily basis or with every bowel movement (Table 1). The degree of anal pain was scored for each patient using visual analogue scale (VAS), scoring 0 to 10 with 0 corresponding to no pain and 10 to the presence of barely severe pain.

Table 1. Symptom questionnaire [13]

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>At least once per year</th>
<th>At least once per months</th>
<th>At least once per week</th>
<th>With every bowel movement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Prolapse</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Manual reduction</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Discomfort / pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Impact on Quality of life</td>
<td>Not at all</td>
<td>Minimal</td>
<td>Moderate</td>
<td>Severe</td>
<td>Very severe</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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</table>

Table 2. Preoperative patient’s characteristics

<table>
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<th>Features</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>men</td>
<td>25</td>
<td>(58.1)</td>
</tr>
<tr>
<td>women</td>
<td>18</td>
<td>(41.9)</td>
</tr>
<tr>
<td>Mean age (year)</td>
<td>67.1</td>
<td>(29~88)</td>
</tr>
<tr>
<td>Goligher hemorrhoid grade</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>13</td>
<td>(30.2)</td>
</tr>
<tr>
<td>3</td>
<td>26</td>
<td>(60.5)</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>(9.3)</td>
</tr>
<tr>
<td>Preoperative symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolapse</td>
<td>33</td>
<td>(76.7)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>15</td>
<td>(34.9)</td>
</tr>
<tr>
<td>Prolapse and bleeding</td>
<td>10</td>
<td>(23.3)</td>
</tr>
<tr>
<td>Anal pain</td>
<td>3</td>
<td>(7.0)</td>
</tr>
<tr>
<td>Discomfort</td>
<td>3</td>
<td>(7.0)</td>
</tr>
</tbody>
</table>
From April 2011 to September 2012, we performed ALTA sclerosing therapy on fifty (50) patients, including four (4) first-degree, six (6) second-degree, twenty-six (26) third-degree and fourteen (14) fourth-degree hemorrhoids according to the Goligher classification (Table 2).

**Symptom Score (Figure 2)**

The symptom score on the questionnaire significantly decreased after ALTA sclerosing therapy. The symptom score (mean±S.D) at the pre-operative day, 1 post-operative month (POM), 3 POM, 6 POM and 12 POM were 14±4, 2±3, 2±4, 3±1 and 1±1, respectively (p<0.0001).

**VAS Score of Anal Pain (Figure 3)**

There was little pain after ALTA sclerotherapy evaluated by VAS. The VAS score (mean±S.D) at pre-operative day, 1 post-operative day (POD), 8 POD, 15 POD and 29 POD were 4.9±2.7, 1.3±1.7, 1.1±1.3, 1.3±1.5 and 0.7±1.3, respectively.

![Figure 2](image1.png)

Figure 2. Symptom score. Symptom score points markedly improved between pre- and post- ALTA sclerotherapy and continued on 12POM. * p<0.0001 One-way ANOVA and Bonferroni test. POM: post-operative month.

![Figure 3](image2.png)

Figure 3. VAS pain score. Pain scale points at post-operative state were about one. POD: post-operative day.
Physical Examination and Anoscopic Findings

Effects were defined as follows:

- **cure** - after bowel movement there is no prolapse of the hemorrhoids, hemorrhage or other discomfort; when examined with an anoscope atrophied internal hemorrhoids have disappeared
- **improvement** - after bowel movement, some hemorrhoids prolapse but return into the anal canal spontaneously; occasional blood or hemorrhage with bowel movements; anoscopic examination reveals some internal hemorrhoids still visible
- **failure** - no improvement.

Figure 4 shows the anoscopic findings in the cured cases. Grade III prolapsed internal hemorrhoids disappeared after ALTA sclerotherapy.

Trans-Anal Ultrasonography

The patients underwent endoanal-endorectal ultrasonography and power Doppler imaging (PDI) was performed. An ultrasound system (Xario™; TOSHIBA, Tokyo, Japan) fitted with endoanal-endorectal probes (PVT-770RT; TOSHIBA) was used.

A 2D ultrasound exploration of the hemorrhoidal tissue was initially carried out. The 2D power-Doppler gate was activated to assess vascularization of the hemorrhoidal tissue. Power Doppler settings were set to achieve maximum sensitivity to detect low velocity flow without noise (frequency, 6.1 MHz; power Doppler gain, 40 dB; dynamic range, 20 dB; edge, 1; time smooth, 7; special smooth, 2; color map, 5; filter, 5; pulse repetition frequency, 16.5 kHz; scale, 3.8). Using combined PDI, the courses of arteries that reached hemorrhoidal piles were followed carefully.

![Figure 4. Effect of ALTA sclerotherapy. Grade III prolapsed internal hemorrhoids disappeared after ALTA sclerotherapy and this effect had continued after 12POM. Before (A) inspection and (B) anoscope examination. After ALTA sclerotherapy (C) inspection and (D) anoscope examination.](image-url)
The 3D volume was then activated to obtain a 3D box from the anal canal. Starting from the highest level (4-6 cm above the anorectal junction) and continuing until the anal verge (1 cm below under line of the internal sphincter muscle), the trans-anal probe was slowly manually pulled through for 60 seconds. Using a fan angle of 0° and a sweep of 50-70 mm, the acquisition box of the 3D volume was placed over the power Doppler window. Using a 3D creation program (Fusion 3D software, TOSHIBA), the pelvic viscera were outlined manually in the transitional plane.

Figure 5. 3D-PDA. The blood flow in hemorrhoidal tissue visualized by 3D-PDA disappeared after ALTA sclerotherapy. Before (A) anterior wall and (B) posterior wall. After ALTA sclerotherapy (C) anterior wall and (D) posterior wall.

Figure 6. PDI. The blood flow signal in hemorrhoidal tissue visualized by PDI disappeared after ALTA sclerotherapy. PDI-area markedly decreased after ALTA sclerotherapy. PDI-area of 11 o’clock, 12-3 o’clock and 6-9 o’clock changed 0.47cm² to 0.06cm³, 1.24cm² to 0.11 and 0.69cm² to 0.03cm², respectively. Before (A) anterior wall and (B) posterior wall. After ALTA sclerotherapy (C) anterior wall and (D) posterior wall.
Ultrasound assessment for blood flow using the three-dimensional power Doppler angiography (3D-PDA) image of the cross-sectional area of the hemorrhoid was performed. During endoanal ultrasonography, the proximal edge of the puborectalis sling was identified to localize the anorectal junction (ARJ). The ARJ was regarded as the best reference point during anorectal ultrasonography. For the axial scan, a trans-anal transducer was positioned approximately 5 to 6 cm from the anal verge; the terminal branches of the superior rectal artery were observed [21]. These vessels were demonstrated in a horizontal plane and identified as hemorrhoidal arteries using power Doppler duplex imaging examinations. Measurements of the power Doppler imaging area (PDI-area) were made using the cursor to outline the power Doppler signal of the hemorrhoid at 1 cm anal side on ARJ.

Figure 5 and Figure 6 show the PDI-area and 3D-PDA image in pre- and post-ALTA sclerotherapy, respectively. From April 2011 to September 2012, we performed ALTA sclerosing therapy on fifty (50) patients, including 4 first-degree, 6 second-degree, 26 third-degree and 14 fourth-degree hemorrhoids according to the Goligher classification.

Blood Flow in Hemorrhoidal Tissue after ALTA Sclerotherapy (Figure 7)

The PDI-area significantly decreased after ALTA sclerotherapy. The PDI-area at pre-operative day, 1 POM, 3 POM, 6 POM and 12 POM were $0.46 \pm 0.50$ cm$^2$, $0.07 \pm 0.06$ cm$^2$, $0.07 \pm 0.07$ cm$^2$, $0.07 \pm 0.07$ cm$^2$ and $0.02 \pm 0.02$ cm$^2$, respectively (p<0.01).

Patient’s Satisfaction for ALTA Sclerotherapy

From January 2009 until December 2010, we performed ALTA sclerotherapy on forty-three (43) patients with second- to fourth-degree hemorrhoids. There were twenty-five (25) men and eighteen (18) women with a mean age of 67.1 years (range: 29 years to 88 years). Overall, thirteen (13) patients had Goligher grade 2 hemorrhoids, twenty-six (26) had Goligher grade 3 and four (4) had Goligher grade 4 hemorrhoids. The mean total injection dose of ALTA was 19.4 ml (range: 6.0 ml to 31.0 ml).

Figure 7. PDI-area. PDI-area markedly decreased between pre- and post-ALTA sclerotherapy and continued on 12 POM. * p<0.0001, ** p<0.001, *** p<0.01 One-way ANOVA and Bonferroni test. POM: post-operative month.
The mean operation time was 19 minutes (range 12 minutes to 33 minutes). All cases were performed under local anesthesia during either day surgery or a one day-hospital stay. The patients' characteristics are summarized in Table 2.

Prolapses and bleeding disappeared immediately after ALTA sclerosing therapy (Figure 8). The resolution of pre-operative symptoms is summarized in Table 3. All cases with bleeding or prolapses were cured or there was improvement after the first post-operative month. At one year after, the rate of successful resolution of bleeding or prolapse remained above 80.0%. According to a simple questionnaire, patient satisfaction rates (satisfied or slightly satisfied) at the point of one (1) month and one (1) year after ALTA sclerosing therapy were 97.7% in both cases (Table 4). There were eight (8) post-operative complications (low grade fever (two); anal pain (two); necrosis at injection site (two); perianal dermatitis (one); bradycardia (one)). There were no serious complications. All cases improved through conservative treatment within one (1) month after ALTA sclerosing therapy.

### Table 3. Resolution of symptoms

<table>
<thead>
<tr>
<th>Preop symptom</th>
<th>Patients (n)</th>
<th>Resolution of symptoms (%successful)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1m later</td>
</tr>
<tr>
<td>Prolapse</td>
<td>33</td>
<td>33 (100%)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>15</td>
<td>15 (100%)</td>
</tr>
<tr>
<td>Prolapse and bleeding</td>
<td>10</td>
<td>10 (100%)</td>
</tr>
<tr>
<td>Anal pain</td>
<td>3</td>
<td>2 (66.7%)</td>
</tr>
<tr>
<td>Discomfort</td>
<td>3</td>
<td>3 (100%)</td>
</tr>
</tbody>
</table>

1 month later, all patients with prolapses and bleeding resolved.
1 year later, the rates of successful prolapse and bleeding resolution were 87.9% and 80.0%.

### Table 4. Overall satisfaction

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
<th>1m later</th>
<th>1yr later</th>
</tr>
</thead>
<tbody>
<tr>
<td>satisfied</td>
<td>36 (83.7%)</td>
<td>38 (88.4%)</td>
<td></td>
</tr>
<tr>
<td>slightly satisfied</td>
<td>6 (14.0%)</td>
<td>4 (9.3%)</td>
<td></td>
</tr>
<tr>
<td>dissatisfied</td>
<td>1 (2.3%)</td>
<td>1 (2.3%)</td>
<td></td>
</tr>
</tbody>
</table>

Regarding patient satisfaction at the point of 1 month and 1 year after ALTA sclerosing therapy, 83.7% and 88.4% were ‘satisfied’ and 14.0% and 9.3% were ‘slightly satisfied’, respectively.
Figure 8. Effect of ALTA sclerotherapy is fast. Grade 3 prolapsed internal hemorrhoids immediately disappeared after ALTA sclerotherapy during operation. Before (A) inspection and (B) anoscope examination. After ALTA sclerotherapy (C) inspection and (D) anoscope examination.

**Evaluation of ALTA Sclerotherapy for Goligher Grade 3 Hemorrhoids: Three-Year Outcomes**

We have performed ALTA sclerotherapy for advanced Goligher grade hemorrhoids since 2009. We analyzed the medical records of one hundred and thirty (130) patients with hemorrhoidal disease who underwent ALTA sclerotherapy at our institution from January 2009 to October 2013. All patients underwent clinical evaluation and physical examination including digital examination and anoproctoscopy for diagnosis of hemorrhoid engorgement and easy-bleeding, prolapsing hemorrhoids. The severity of hemorrhoidal disease was graded according to Goligher’s classification.

Patient’s characteristics of both groups, Goligher grade 2 and 3, are summarized in Table 5. Thirty-one (31) patients were grade 2 and ninety-nine (99) patients were grade 3. All patients were treated with ALTA sclerotherapy. Patients with grade 3 were injected with a significantly higher dose of ALTA than grade 2 (p=0.0004). The operation time for grade 3 was significantly longer than that of grade 2 (p=0.01).

No significant differences were observed in the cumulative recurrence rate after ALTA sclerotherapy between grades 2 and 3 (Log-rank test: p=0.33) (Figure 9). The one-year cumulative recurrence rates of grade 2 and 3 were 3.7% and 6.8% respectively. The two-year cumulative recurrence rates of grade 2 and 3 were 3.7% and 8.5% respectively. The three-year cumulative recurrence rates of grade 2 and 3 were 3.7% and 10.6% respectively. ALTA sclerotherapy is as effective a treatment for grade 3 haemorrhoids as it is for grade 2.

There were nine (9) post-operative complications (bleeding in two (2) cases; rectal ulcer in three (3) cases; diarrhea in two (2) cases; low grade fever in one (1) case and a feeling of anal discomfort in one (1) case). No significant differences were observed in the cases of post-operative complications, two (2) grade 2 and seven (7) grade 3 (qui-square test: p=0.91) (Figure 10). All cases improved through conservative treatment. There was no delayed hemorrhage, although five (5) cases who had heart disease with anticoagulant did not withdraw.
Table 5. Patient’s characteristics in both groups, grade 2 and grade 3

<table>
<thead>
<tr>
<th>Goligher classification</th>
<th>grade 2</th>
<th>grade 3</th>
<th>statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>31</td>
<td>99</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>14</td>
<td>57</td>
<td>N.S (p=0.22)</td>
</tr>
<tr>
<td>female</td>
<td>17</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Age (y.o)</td>
<td>64±15</td>
<td>64±15</td>
<td>N.S (p=0.90)</td>
</tr>
<tr>
<td>Injection dose of ALTA (ml)</td>
<td>14.5±8.8</td>
<td>19.2±6.3</td>
<td>p=0.0004</td>
</tr>
<tr>
<td>Operation time (minutes)</td>
<td>17±5</td>
<td>21±7</td>
<td>p=0.01</td>
</tr>
<tr>
<td>Follow up time (months)</td>
<td>25.5±13.7</td>
<td>22.7±12.6</td>
<td>N.S (p=0.29)</td>
</tr>
</tbody>
</table>

N.S: not significant.

Figure 9. Cumulative recurrence rate. Cumulative recurrence rate was not significant difference in both groups, grade 2 and grade 3 (Log-rank test: p=0.33).

<table>
<thead>
<tr>
<th>Recurrence rate</th>
<th>1-year</th>
<th>2-year</th>
<th>3-year</th>
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<tbody>
<tr>
<td>Goligher grade 2</td>
<td>3.7%</td>
<td>3.7%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Goligher grade 3</td>
<td>6.8%</td>
<td>8.5%</td>
<td>10.6%</td>
</tr>
</tbody>
</table>

Figure 10. Frequency of occurrence of complication and recurrence. There was no significant difference in complication and recurrence in groups, grade 2 and grade 3, by qui-square test, respectively. N.S: not significant.


Discussion

The treatment for internal hemorrhoids is gradually shifting to minimally invasive surgery. Conventional hemorrhoidectomy used to be the most widely used surgical procedure. Although this procedure was very effective, it was painful and potentially affected the mechanism of anal continence [7]. Over the years, alternative minimally invasive techniques have been developed including stapled hemorrhoidopexy, also known as PPH and transanal hemorrhoidal dearterialisation and hemorrhoidopexy, also known as THD [5-7, 12-14].

ALTA sclerotherapy is popular with patients with symptomatic internal hemorrhoids in Japan. The reasons are that ALTA sclerotherapy is especially superior about three points, (1) minimally invasive, (2) high satisfaction and (3) safety.

Minimally Invasive

ALTA sclerotherapy causes less pain. The VAS score after ALTA sclerosing therapy was 1.3 on post-operative day 1. It was reported that the VAS score on post-operative day 1 after PPH and THD was 5.1 and 3.1 respectively [3]. There were no serious complications after ALTA sclerosing therapy when the four-step injection procedure was correctly undertaken. However, if the four-step injection procedure is not observed, occasional and serious complications may occur.

It is very important to note that ALTA sclerosing therapy must be undertaken according to the correct four-step injection method, unlike conventional sclerosing treatment. Furthermore, it is important that we determine the indicators for deciding on ALTA sclerosing therapy. ALTA should not be used as a treatment for hemorrhoids associated with skin tags, anal polyps, mixed hemorrhoids with predominant external hemorrhoids and acute irreducible hemorrhoids. If we found internal hemorrhoids with skin tags or anal polyps, we firstly resected the skin tags, anal polyps or external hemorrhoids, and then performed ALTA injections for the internal hemorrhoids.

High Satisfaction

Patients were highly satisfied with ALTA sclerosing therapy as a treatment for internal hemorrhoids. In this study, overall satisfaction at one (1) month and one (1) year after ALTA sclerosing therapy was 97.7%. In the Japanese literature, Matsuda et al. reported that overall satisfaction of ALTA sclerosing therapy was over 90% and concluded that ALTA sclerosing therapy matched the needs of patients with symptomatic internal hemorrhoids [21]. High satisfaction of ALTA sclerotherapy may be based on three reasons. First, one reason is that unpleasant symptoms disappear immediately on the first post-operative day in almost all cases.

Second, patients experience little post-operative pain and no serious complications. Third, the cost can be reduced by one-tenth of the cost of ligation and excision, because ALTA sclerosing therapy entails only day-surgery or a one-day hospital-stay, rather than a long hospital stay.
Safety

ALTA sclerotherapy had little serious complications, especially no delayed hemorrhage requiring an operation. Yano et al. reported that the presence or absence of antithrombotic treatment did not affect the efficacy rate or the occurrence of complications, including delayed hemorrhage, with ALTA sclerotherapy [23]. In our experience, we had no delayed hemorrhage.

The ALTA sclerotherapy is epoch-making treatment for internal hemorrhoids. We presented that ALTA sclerotherapy was effective for the grade 2, grade 3 and grade 4 internal hemorrhoids [4]. In Japan, ALTA sclerotherapy has become gradually recognized as the first choice for treating internal hemorrhoids in recent years with the popularization of the four-step injection method. Nowadays, ALTA sclerotherapy for internal hemorrhoids has been performed in over three hundred thousand (300,000) cases in Japan since the year 2000.

In conclusion, ALTA sclerosing therapy is very popular with patients as a minimally invasive and curable treatment for internal hemorrhoids including advanced grade hemorrhoids. We hope that ALTA sclerotherapy will be recognized as the first choice treatment for internal hemorrhoids around the world.

References


