Short- and Long-term 5-year Clinical Outcomes of Doppler-guided Hemorrhoidal Artery Ligation and Rectoanal Repair

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Abstract

Introduction: To evaluate long-term clinical outcomes after Doppler-guided hemorrhoidal artery ligation (DG-HAL) and rectoanal repair (RAR) for internal hemorrhoids.

Methods: The study included patients with grades II or III internal hemorrhoids who underwent DG-HAL and RAR at our institution. Clinical characteristics, short- and long-term outcomes were prospectively collected and analyzed.

Results: Out of 36 patients, 28 had complete data and were included in the study. The mean age was 51.1 ± 15.0 years. The two most common presenting symptoms were mucosal prolapse (100%) and bleeding (82.1%). Median duration of symptoms was 20 months (range, 0.5- 240 months). The mean number of sutures was 5.6 ± 0.9 with mean operative time of 40.9 ± 9.9 minutes. The pain score, using VAS pain tool, at 24 hours after surgery was less than or equal to 5 in almost all patients (96.4%). Urinary retention, infection, anal fissure and thrombosed external hemorrhoids occurred in six (21.4%), two (7.1%), two (7.1%) and one (3.6%) patient (s), respectively. At five years, prolapse and bleeding were the two most common recurrent symptoms occurring in eight (28.6%) and six patients (21.4%) respectively.

Conclusions: Short-term clinical outcomes of patients with grades II or III internal hemorrhoids who underwent DG-HAL and RAR were modest with minor complications. Long-term outcomes were not improved when compared to historical standard open hemorrhoidectomy, while one fourth experienced recurrence.

Keywords: Doppler-guided hemorrhoidal artery ligation, long-term outcomes, rectoanal repair.

ผลลัพธ์การรักษาระยะสั้นและระยะยาวที่ 5 ปี ในโรคริดสีดวงทวารด้วยวิธี Doppler-guided Hemorrhoidal Artery Ligation and Rectoanal Repair

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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาผลลัพธ์ระยะยาวของการรักษาโรคริดสีดวงทวารด้วยวิธีการผ่าตัด doppler-guided hemorrhoidal artery ligation (DG-HAL) และ rectoanal repair (RAR)

วิธีดำเนินการวิจัย : ศึกษาในผู้ป่วยที่เป็นริดสีดวงทวารระยะที่ 2 และ 3 ที่ได้รับการผ่าตัดด้วยวิธี DG-HAL และ RAR ในวชิรพยาบาล โดยรวบรวมข้อมูลลักษณะอาการและผลของการรักษาระยะสั้น และระยะยาว

ผลการวิจัย: การติดตามผลการรักษาระยะยาวด้วยวิธีการผ่าตัด DG-HAL ในผู้ป่วย 28 คน จาก 36 คนที่ได้รับการผ่าตัดรักษาริดสีดวงทวารด้วยวิธี DG-HAL และ RAR ระหว่างเดือนมิถุนายน 2551 ถึงเดือนมิถุนายน 2558 พบว่าอายุเฉลี่ยของผู้ป่วยอยู่ที่ 51.1 ± 15.0 ปี โดยอาการที่พบเรียงจากมากที่สุดคือ มีติ่งเนื้อยื่นออกจากรูทวารและเลือดออก ร้อยละ 100 และ 82.1 ตามลำดับ ค่าเฉลี่ยของระยะเวลาที่มีอาการคือ 20 เดือน (0.5 - 240 เดือน) ค่าเฉลี่ยตำแหน่งของการเย็บเส้นเลือดคือ 5.6 ± 0.9 ตำแหน่ง โดยค่าเฉลี่ยระยะเวลาการผ่าตัดอยู่ที่ 40.9 ± 9.9 นาที ค่าเฉลี่ยคะแนนความปวดที่ 24 ชั่วโมงหลังผ่าตัด ส่วนใหญ่น้อยกว่าหรือเท่ากับ 5 คิดเป็นร้อยละ 96.4 ภาวะแทรกซ้อนหลังผ่าตัดเรียงจากมากไปน้อยได้แก่ ภาวะปัสสาวะคั่งเฉียบพลัน การติดเชื้อ แผลปริขอบทวารหนัก การอักเสบของริดสีดวงทวารภายนอก ร้อยละ 21.4, 7.1, 7.1 และ 3.6 ตามลำดับ ผลการติดตามที่ระยะ 5 ปีหลังผ่าตัดพบว่า ภาวะติ่งเนื้อยื่นออกทางทวารหนักและเลือดออกถือเป็นอาการที่กลับเป็นซ้ำได้มากที่สุด โดยคิดเป็นร้อยละ 28.6 และ 21.4

สรุป : ผลการผ่าตัดแบบ DG-HAL และ RAR ในผู้ป่วยริดสีดวงทวารระยะที่ 2 และ 3 เป็นการรักษาแบบใหม่ ที่มีภาวะแทรกซ้อนน้อย ในขณะเดียวกันผลระยะยาวของการรักษายังมีการกลับเป็นซ้ำซึ่งพบได้ 1 ใน 4 ของจำนวนผู้ป่วยที่ได้รับการผ่าตัด

Introduction

Hemorrhoids are malformations of highly vascular sinusoidal cushions that lie along the anal canal[1-3]. It is a very common anorectal disorder, which occurs in 39% – 64% of the adult Treatment for hemorrhoids depends on grade and severity of symptoms[6-8]. In patients with grades III and IV internal hemorrhoids, surgical treatment staple hemorrhoidopexy or hemorrhoidectomy are commonly used[9]. Staple hemorrhoidopexy may post-operative bleeding at surgical sites or pelvic abscesses and sepsis[10-16], while hemorrhoidectomy, which has long been used, may cause anal pain and slow wound healing[15,17-19]. Recently, Doppler-guided hemorrhoidal artery ligation (DG-HAL) with without rectoanal repair (RAR) has been introduced as a minimally invasive surgical option. DG-HAL is a simple ligation of hemorrhoidal arteries; while RAR is a surgical mucopexy fixing hemorrhoidal tissues rectal mucosa above the dentate line. Advantages of DG-HAL/ RAR over other surgical techniques are minimal blood loss, less post-operative pain, rapid wound healing, leading to rapid recovery and short hospital stay[19-22]. Several studies reported no complications and low incidence of recurrence at months[23] or 1-3 years after surgery[24-28]. Only a few studies reported long-term clinical outcomes up to 5 years, or longer after DG-HAL[21,29]. The aim of this study was to evaluate long-term clinical outcomes in patients with grades II or III internal hemorrhoids who underwent DG-HAL and RAR.

Methods

The study was approved by the Ethics Committee of our institution. Inclusion criteria were patients who had grade II and grade III internal hemorrhoids according to the Goligher's classification[5]. Data of patients who were admitted to the Colorectal Surgical Unit, Department of Surgery, Faculty of Medicine Vajira Hospital June 2008 and June 2010 and underwent surgery single physician (S.P.) were prospectively collected. Exclusion criteria were patients who had the following conditions: immunocompromised status, receiving anti-coagulant drugs, active inflammatory disease, or other anorectal disease. Patients with available data were also excluded.

Patients aged 50 years and older who presented with rectal bleeding underwent colonoscopy to evaluate the entire colon to other non-hemorrhoidal colorectal disease before the operation. Informed consent was obtained to colonoscopy and surgical procedure.

Spinal anesthesia was given to all patients before putting them into Modified Jackknife position. The operative procedure was performed using a proctoscope equipped with a Doppler probe and a light source (A.M.I. GmbH, Feldkirch, Austria). The ultrasound waves generated by this device yield information regarding the appropriate vessels to be ligated at level 3-5. Thus, the target arteries identified within the Doppler operative window were transfixed by a figure-of-eight suture using 2–0 absorbable polyglycolic acid suture material with a 5/8-inch needle. The six main of the hemorrhoidal arteries, which are usually located at 1, 3, 5, 7, 9, and 11 o'clock of the lower rectal circumference, were the main targets. We performed RAR and closed with 3-0 absorbable sutures in all patients with internal hemorrhoids undergoing DG-HAL procedure. Hemorrhoidectomy was additionally performed for co-existing large external hemorrhoids.

Post-operative pain was assessed by visual analogue scale pain score (VAS) at 6 and 24 hours after surgery. Oral acetaminophen 500 mg and tramadol 50 mg were routinely given to all In addition, when the VAS was greater than 5, intravenous meperidine was given. We scheduled the first post-operative follow up within two weeks after operation to assess any early complications. Subsequent follow-up visits were at 1 month, 2 months and 6 months at out-patient clinic. Final follow-up was performed at 5 years by telephone to enquire about patients' health status.

Data collected were: age; gender; presenting symptoms and duration; grading of internal hemorrhoids; presence of co-existing external hemorrhoids; details of operative data, pain score (VAS), and meperidine usage; intraoperative, early (within 14 days) and short-term (within 6 months) post-operative complications; length of hospital stay, and persistence of symptoms. Acute urinary retention was defined as inability to void despite having a full bladder, requiring intermittent catheterization. Major bleeding was defined when bleeding was observed from surgical site with decreased hematocrit greater than 3 g/dl, requiring blood transfusion or surgical intervention for hemostasis. Fever was defined as body greater than 37.8 °C.

Data were analyzed using SPSS statistical software, version 22.0 (IBM Corporation, Armonk, NY, USA). Descriptive statistics were used to demographic data and were summarized as with percentage, mean with standard deviation or median with range. $P < 0.05$ was considered statistically significant.

Results

A total of 36 patients underwent DG-HAL/RAR during the study period. Eight patients had incomplete data leaving 28 patients included in the study. Mean age was 51.1 ± 15.0 years (range, 26-79 years). Three patients (10.7%) had grade II and 25 (89.3%) had grade III internal hemorrhoids. Two patients had previously had hemorrhoidectomy at 40 months and 148 months prior to this episode.

Presenting symptoms of patients are shown in Table 1. The two most common symptoms were prolapse (100%) and bleeding (82.1%). Duration of symptoms ranged from 0.5 month to 240 months (median, 20 months). The duration was longer in female than male; 65.0 vs 36.8 months ($p = 0.030$). All underwent DG-HAL and 25 (89.3%) had RAR procedure. The mean number of sutures for HAL was 5.6 ± 0.9 (range, 3-6). The most and least common sites of suture were at 7 o'clock (100%) and 9 o'clock (82.1%), respectively. The mean operative time was 40.9 ± 9.9 minutes (range, 25-60 minutes). No intraoperative complications were encountered. Details of operation are shown in Table 2.

Table 1:

Presenting symptoms and duration of symptoms of the study population (n = 28)

	Study population (n = 28)
Presenting symptom, n (%)	
Pain	12 (42.9)
Rectal discharge	0
Bleeding	23 (82.1)
Perianal itching	3 (10.7)
Prolapse	28 (100)
Associated symptom, n (%)	
Constipation	11 (39.3)
Incontinence	0
Duration of symptom (months)	
Mean (standard deviation)	48.9 (67.7)
Range (minimum – maximum)	20 (0.5 – 240)

Table 2:

Operative characteristics

Characteristic	Study population (n = 28)
Operative procedure, n (%)	
DG-HAL	28 (100)
RAR	25 (89.3)
Hemorrhoidectomy	1 (3.6)
Duration of operation (minutes)	
Mean (SD)	40.9 (9.9)
Range (minimum – maximum)	40 (25 – 60)
Number of DG-HAL sutures, n (%)	
Mean (SD)	5.6 (0.9)
Range (minimum – maximum)	6 (3 – 6)
Site of HAL, n (%)	
At 1 o'clock	27 (96.4)
At 3 o'clock	24 (85.7)
At 5 o'clock	27 (96.4)
At 7 o'clock	28 (100)
At 9 o'clock	23 (82.1)
At 11 o'clock	27 (96.4)
Number of RAR, n (%)	
Mean (SD)	3.0 (1.0)
Range (minimum – maximum)	3 (0 – 4)
Site of RAR, n (%)	
At RA position	20 (71.4)
At LA position	9 (32.1)
At RP position	19 (67.9)
At LP position	10 (35.7)
At RL position	4 (14.3)
At LL position	15 (53.6)

DG-HAL = Doppler-guided hemorrhoidal artery ligation; LA = left anterior; LL = left lateral; LP = left posterior; RA = right anterior; RAR = rectoanal repair; RL = right lateral; RP = right posterior; SD = standard deviation.

Table 3:

Post-operative findings within 14 days post operation

Finding	Study population (n = 28)
Dose of meperidine requirement, n (%)	
Not required	10 (35.7)
≤ 50 mg	15 (53.6)
> 50 mg	3 (10.7)
Patients having complications, n (%)	10 (35.7)
Type of complication, n (%)	
Urinary retention	6 (21.4)
Fever	2 (7.1)
Acute fissure	2 (7.1)
Thrombosed external hemorrhoids	1 (3.6)

Post-operative complications were found in 15 patients (53.6%). Among these, 10 (35.7%) occurred within 14 days post operation and 11 (39.2%) were within six months. Regarding the early complications within 14 days, six patients (21.4%) had urinary retention, two (7.1%) had fever, two (7.1%) developed acute anal fissure and one (3.6% had thrombosed external hemorrhoids (Table 3).

Five patients (17.9%) had mucosal prolapse within six months after surgery. Two (7.1%) had minimal and intermittent bleeding, according to either patient self-reports, or findings from the follow-up physical examination. The other two patients had itching or discharge (one each). Table demonstrates short-term follow-up findings.

All 28 patients had long-term follow-up data for their clinical course and outcomes. At 5 years, ten patients (35.7%) reported symptoms of prolapse, itching and discharge to various degrees. The two most common symptoms were prolapse found in eight patients (28.6%) and bleeding found in six patients (21.4%). Three patients (10.7%) had symptoms requiring additional treatment with either rubber band ligation (one patient), hemorrhoidectomy (one patient) or conservative treatment (one patient who had thrombosed external hemorrhoids).

Discussion

Many techniques of surgical interventions reported in various literature include open hemorrhoidectomy, and closed or semi-closed hemorrhoidectomy[30]. LigaSure™ and Harmonic® hemorrhoidectomies[31] as well as stapled hemorrhoidopexy are commonly used techniques From the surgical point of view, open and closed hemorrhoidectomies result in fewer hemorrhoid recurrences but are accompanied by more postoperative complications and slower recovery. In contrast, stapled hemorrhoidopexy is associated with decreased postoperative pain and faster recovery but has higher recurrence rates[32,33]. advances in surgical approaches, there has been best operative technique because each procedure has advantages and some disadvantages.

In 1995, DG-HAL was first introduced in Japan as a minimally invasive technique to correct hemorrhoids by ligation of the affected vessels[34].

Table 4:

Recurrent symptoms at 1 month, 2 months, 6 months and 5 years post operation (n=28)

Recurrent symptom	At 1 month n (%)	At 2 months n (%)	At 6 months n (%)	At 5 years n (%)
Without symptom	19 (67.9)	23 (82.1)	23 (82.1)	18 (64.3)
With symptom(s)*	9 (32.1)	5 (17.9)	5 (17.9)	10 (35.7)
Bleeding	6 (21.4)	2 (7.1)	2 (7.1)	6 (21.4)
Prolapse	7 (25.0)	5 (17.9)	5 (17.9)	8 (28.6)
Itching	1 (3.6)	1 (3.6)	1 (3.6)	1 (3.6)
Discharge	1 (3.6)	1 (3.6)	1 (3.6)	3 (10.7)

* One patient may have one or more symptoms

It has advantages over other techniques due to its ability to identify target vessels by using doppler ultrasound. Many studies reported excellent outcomes by DG-HAL in terms of a one-day setting[30], rapid time to first bowel movement[31], improvement of bleeding and prolapse scores, earlier return to normal daily activities[5,31,32], minimal post-operative pain and low incidence of complications[31].

To date, there have been only few studies which evaluated long-term outcomes with variable numbers of years after DG-HAL[24-29,36]. Of these, only two studies reported a real long-term follow-up period of five or more years[21,29]. Our study also had complete data of long-term 5-year follow up. different characteristics between both studies and our study were observed. The study of Avital et al.[29] included patients with grade II-III hemorrhoids who underwent only DG-HAL while the other study by Scheyer et al. [21] included patients with grades II–IV hemorrhoids who underwent either DG-HAL (for grade II hemorrhoids) or RAR (for grades III or IV hemorrhoids). Our study included only patients with grade II and grade III internal hemorrhoids. All except three patients underwent DG-HAL and RAR. Different inclusion criteria and number of operative procedures may influence the outcomes.

Our study evaluated both short-term and long-term outcomes of DG-HAL and RAR. Demographic data showed significantly longer duration of symptoms in female than male. This may be due to the culture of Thai women being more patient and shy about medical consultations in this part of body. The median number of in our study was six, including the 1, 3, 5, 7, 9 and o'clock positions. These are anatomical locations of large hemorrhoidal arteries. Other studies in early years performed 7-11 ligations or as many as possible due to their awareness of the learning curve of surgeon experience for HAL and to good outcomes[28,37]. The mean operative time of 41 minutes in our study was longer than the average of 19-35 minutes observed in others studies[26,28,29,36]. This was clearly due to an additional procedure of RAR performed in almost all patients. We believed that this RAR added benefits to hemorrhoid correction by strengthening the rectal wall and its vasculature, and should, therefore, better reduce symptoms and rates of recurrence. This addition of RAR may also be responsible for our slightly higher 6-hour and 24-hour postoperative pain scores (5.6 and 3.0) compared to those found in previous reports[25,26,29,36]. Furthermore, the sutures close to the dentate line in RAR procedure generally result in more pain than the DG-HAL procedure only. However, this pain level was mild and still considered as not clinically important compared to other techniques of open hemorrhoidectomy and semi- closed hemorrhoidectomy.

Our 21% rate of postoperative urinary retention detected in the early post-operative ranged from 1.3–36% reported by others[24,26,38,39]. The causes may probably be multi-factorial e.g. an additional RAR procedure as well as an effect of spinal anesthesia. The patients in our study had longer mean length of hospital stay than those in other studies: 4.8 days vs 0.1–1.6 days[24,25,29,36]. Actually, it might be inappropriate to compare this outcome of our study to others because our policy was to ensure that no fecal impaction or early complications occurred, so all patients were observed for a minimum period of 3 days after surgery.

At 1-month post operation, we found bleeding symptoms persisted in 22% of patients. This rate was higher than those found in other studies (3–4%)[24,26]. This might lie on the definition and the record of 'bleeding' in each study. Our study recorded any bleeding regardless of the amount as 'bleeding' while the other studies did not provide any definition at all. Nevertheless, the degree of bleeding in our study was minimal. on the fact that the DG-HAL is a procedure in the affected vessels are ligated, bleeding would therefore not cease immediately after the because it takes time to decrease blood flow to hemorrhoidal plexus. This was demonstrated in our study as we found the number of patients with bleeding decreased over time. Similar to bleeding, it takes time to reduce prolapse symptoms. At a 1-month follow up, we found prolapse symptoms persisted in seven patients (25%). This finding was comparable with the result of Scheyer et al.[21] who reported a 26% rate of persistent prolapse at two months of follow-up.

Focusing on the short-term (six months) outcomes, we found that 82.1% of our patients remained asymptomatic. This rate was slightly than that reported by Avital et al.[29] who performed DG-HAL in 100 patients with symptomatic grades II or III hemorrhoids. Their study found 89% of were free of symptoms at 12 months. Aside from the different time point of assessment, different proportions of grade III internal hemorrhoids, which generally had a lower rate of success than grade II[29], may account for the different rates of success. Fewer patients in our study had no symptoms compared to Avital et al.'s study, because our had more percentages of grades III hemorrhoids: 89% compared to 81% in their study.

At a 5-year follow up, there were no major recurrent symptoms found in our patients. The most common recurrent symptom of prolapse which was identified in 29% of our patients was only slightly higher than the 26% and 24% reported by Avital et al.[29] and Scheyer et al.[21] who found prolapse symptoms in their patients at 5-year and 6.5-year follow up, respectively. A comparison across the studies might be difficult as the difference among studies may lie in many reasons (e.g. detailed surgical techniques, process of follow-up or how data were obtained, characteristic features of patients grade II, grade III or grade IV including their predisposing factors to hemorrhoids in each study). The second most common recurrent symptom identified at long-term follow-up in all 3 studies, ours, Avital et al.[29], and that of Scheyer et al.[21], was bleeding; however, ranging from 21%, 13%, and 3%, respectively. Of note, as many as 35% of the patients in the study of Scheyer et al. were lost to follow-up. Moreover, 20% of the patients were reported to have mixed recurrent symptoms. Hence, the 24% rate of prolapse and 3% rate of bleeding could be underestimated.

One limitation of our study was a relatively small sample size. Thus, we could not compare outcomes between grade II and grade III The strength of our study was all patients surgery by single experienced surgeon, so surgical techniques applied to all patients were consistent. Furthermore, all patients were closely observed until day 3 post operation. Therefore, data on postoperative complications were reliable. Lastly, we had authentic long-term follow up data of all patients. Hence, complication and recurrence rates were as accurate as short-term follow up data.

In conclusion, DG-HAL and RAR procedures are safe and effective for patients with grades II and III hemorrhoids. Future research with a larger

number of patients, or with a comparison of DG-HAL and RAR with other surgical techniques would be useful. Quality of life of patients should also be investigated as another outcome of interest.

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