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DOPPLER- GUIDED HAEMORRHOIDAL ARTERY LIGATION (DGHAL), RECTOANAL REPAIR (RAR), SUTURED HAEMORRHOIDOPEXY (SHP) AND MINIMAL MUCOCUTANEOUS EXCISION (MMCE) FOR GRADE III-IV HAEMORRHOIDS: A MULTICENTER PROSPECTIVE STUDY OF SAFETY AND EFFICACY

Running head: DGHAL and RAR for hemorrhoids

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ABSTRACT

Objective: The isolated use of Doppler-guided haemorrhoidal artery ligation (DGHAL) may fail for advanced haemorrhoids (HR) (grades III, IV). Suture haemorrhoidopexy (SHP) and mucopexy by rectoanal repair (RAR) result in haemorrhoidal lifting and fixation. A prospective evaluation was performed to evaluate the results of DGHAL combined with adjunctive procedures.

Methods: The study included 147 patients with haemorrhoids (males:102; grade III:95, IV:52) presenting with bleeding (73%) and prolapse (62%).

Results: More ligations were required for grade IV than III haemorrhoids (10.7+2.8 vs 8.6+2.2, $p<0.001$). SHP (28 patients) and RAR (18 patients) at 1-4 positions were deemed necessary in 46 (31%) patients. Minimal (muco-)cutaneous excision (MMCE) was added in 23 patients. SHP/RAR were applied more frequently in Grade IV HR (60% vs 16%, $p<0.001$). In patients not having MMCE, SHP/RAR were added in 57% of grade IV cases ($p<0.001$). Complications included residual prolapse (10; 2 second surgery), bleeding (15; 2 second DGHAL), thrombosis (4), fissure (3) and fistula (1). No analgesia was required by 30%, 31%, 16%, 14% of the patients on days 1-3, 4-7 and >7 respectively. SHP/RAR was associated with greater discomfort (17% vs 6%, $p<0.001$). No differences were found between SHP and RAR. At an average follow-up of 15 months, 96% of patients were asymptomatic and 95% were satisfied.

Conclusions: DGHAL with the selective application of SHP/RAR is a safe and effective technique for advanced grade haemorrhoids.

INTRODUCTION

Advanced symptomatic haermorrhoids have been managed by various techniques [1-4]. Postoperative pain, slow convalescence and occasional long-term complications have encouraged the development of less invasive techniques[5, 6], some based on anatomical and histological studies[7-15]. Reduction of the haemorrhoidal mass by reducing the blood supply was proposed by Morinaga in 1995[16]. Doppler-guided haemorrhoidal artery ligation (DGHAL) relies on proctoscopic-assisted and Doppler-guided precise identification and selective ligation of the haemorrhoidal plexus feeding vessels. Initially it was shown to be particularly effective in controlling bleeding, but its application to grade IV haemorrhoids often resulted in failure, mainly due to its inability to correct the prolapse that accompanies advanced grade haemorrhoids[17, 18]. As a result DGHAL has been modified to achieve a combination of haemorrhoidal artery ligation and proctoscopic-assisted transanal rectal mucopexy of the prolapsing tissue: rectoanal repair (RAR). Essentially this is an evolution of various suture mucopexy and haemorrhoidopexy techniques that have been previously described but have never gained widespread acceptance[19-27]. In addition a prominent external component may not be adequately controlled by this combination and may require minimal muco-cutaneous excision (MMCE) of protruding anoderm and perianal skin or minor cutaneous excision of skin tags.

DGHAL was applied as the basic procedure in this series of patients. Suture hemorrhoidopexy (SHP), mucopexy by RAR, and MMCE were added as adjunctive interventions when required. We report the results of a prospective application of this treatment policy with reference to safety and efficacy.

PATIENTS AND METHODS

A total of 147 patients with symptomatic Grade III (95) and IV (52) haemorrhoids (mean age: 45,5, males: 102) were operated between November 2005 and May 2007. Participating institutions included one academic, two public and two private hospitals. Patients with a follow-up of less than six months, acute thrombosis and perianal abscess or fistula were excluded. Only patients with Grade III or IV haemorrhoids were included. A complete medical history was taken with emphasis on haemorrhoidal symptoms, previous treatment and concurrent anorectal conditions. Outcome measures included symptom relief, post-procedure pain, incidence of complications and patient satisfaction. Patients were reviewed at one, six and 12 months.

The operation was performed with the patient in the lithotomy position, under local anaesthesia with intravenous sedation, spinal anaesthesia or general anaesthesia depending on the patient's or surgeon’s preference. A specially developed anoscope incorporating a side viewing Doppler probe (HAL-Doppler II, A.M.I, Austria) was used to locate the submucosal terminal branches of the superior haemorrhoidal artery, as previously described[16, 18]. A variable number of “figure of eight” absorbable sutures were placed (Fig. 1) and a second Doppler assessment was made to identify any remaining signals suggesting a patent artery which was then ligated.

The use of SHP, RAR and MMCE was at the surgeon’s discretion and dictated intraoperatively by the persistence of any remaining nodules protrusion or mucocutaneous prolapse. When SHP was decided upon, a Pratt retractor was inserted transanally and a running suture was applied to the site

of remaining prolapse (Fig. 1). The most distal stitch remained above the dentate line and was tied to the most cranial stitch to lift the prolapse. The introduction of RAR (AMI Austria) facilitated haemorrhoidopexy by confining the mucosal lift to the sites of residual protrusion. The instrument is equipped with an outer sleeve attached to the HAL handle, which enables the operating window of the proctoscope to be changed from the “ligating” to the “pexy” position (Fig. 1, 2). This results in exposure of a wider mucosal area allowing the prolapsing tissue to come into view through the window, rendering the stiching and subsequent lifting of the remaining haemorrhoidal cushion easier (Fig. 1, 2). In cases with residual prolapsing piles, excessive skin tags or a prominent external component, MMCE with primary closure with a fine absorbable suture was added in selected cases.

All patients were discharged on the first postoperative day. Subsequent management included a high-residue diet, stool softeners and warm sitz baths. Pain medication consisting of nonsteroidal anti-inflammatory agents and oral narcotics were prescribed as needed at discharge. Different types and doses of analgesics were used depending on the surgeon’s preference and the patient’s tolerance. The duration of the period that analgesics were required was therefore used as a crude estimate of post-operative pain.

Statistical analysis was performed using the t-test for continuous data and Fisher’s exact test or the chi-squared test for categorical data. Differences were considered to be statistically significant at the 5% level. Data were analyzed by using SPSS for windows, version 12 (SPSS, Inc., Chicago, IL, USA).

RESULTS

The presenting symptoms included bleeding (73%), prolapse (62%), pain (14%) and thrombosis (17%). Six patients had had a previous intervention for haemorrhoids including: PPH (2), Milligan-Morgan (3) and anal dilatation (1). The combination of procedures used is illustrated in Figure 3. SHP and RAR was added to DGHAL in 46 (31%) patients. MMCE was added in nine of the SHP/RAR cases and in 23 patients overall. Lateral internal sphincterotomy was added in 12 cases, due to the concomitant presence of an anal fissure. Analysis was performed for the whole group of 147 patients and for the 124 patients (non-MMCE group) who did not have an excisional procedure (Table 1).

The median number of ligations placed was 9 (range: 4-16). Median values were 9 and 10 for Grade III and IV haemorrhoids, respectively (range: 4-16). Overall, significantly more ligations were required for grade IV haemorrhoids (mean $\pm$ SD: 10.7+2.8 vs 8.6+2.2, $p<0.001$). Significantly more ligations were used at the DGHAL stage of the procedure when SHP/RAR was added (mean $\pm$ SD: 10.4+2.5 vs 8.7+2.4, $p<0.001$) (Table 1). For the whole group of patients, the addition of SHP/RAR occurred more frequently in Grade IV haemorrhoids (60% of Grade IV vs 16% of Grade III cases, $p<0.001$) (Fig. 4). For the non-MMCE group, SHP/RAR was added more often in Grade IV cases (57% vs 17%, $p<0.001$) (Table 1).

At the end of the first month, 10 patients had residual prolapse. None had had MMCE as part of the initial procedure (Table 1) and nine had had a DGHAL only. The remaining patient had been treated with DGHAL-SHP and did not require further treatment (Table 1). The efficacy rate for SHP/RAR was 97.8% (45/46 cases), although two patients subsequently required reintervention at two and six months postoperatively (hemorrhoidectomy and RAR) (Table 1).

At longer follow-up six of the ten patients remain well with minimal protrusion and skin tags (Table 1).

Among the 91 patients who presented with prolapse, excluding the two who required further correction, the operative strategy had an overall success rate (complete or significant improvement) of 97.8%. Minor bleeding occurred in 15 patients (12 non-MMCE patients) and two patients (one after DGHAL-SHP) had persistent bleeding at three and six months post-operatively. Both required a second DGHAL procedure (Table 1). Additional complications included four episodes of thrombosis, three fissures and one submucosal fistula.

Analgesic requirements were as follows: none (30%), days 1-3 (31%), days 4-7 (16%) and days >7 (14%). Only 43 DGHAL (35 DGHAL, 9 DGHAL+MMCE) patients required no pain medication at all. The 13 (14%) patients (6 DGHAL, 6 DGHAL-SHP and 1 DGHAL-RAR, 3 MMCE), who required analgesia for more than seven days described the anal discomfort as tenesmus or a sensation of fullness. In the non-MMCE group analgesia use was significantly related to the SHP/RAR procedure ($p<0.01$) (Table 1). SHP/RAR was also related to prolonged discomfort (17% vs 6% overall; 19% vs 3.5% non-MMCE patients, $p<0.001$) (Table 1). No differences were detected between SHP and RAR (Table 1).

At the first post-operative visit, 90.5% of patients reported complete recovery by the end of the first week. With the exception of six patients with persisting skin tags or minimal prolapse, the remaining 118 (96%) patients of the non-MMCE group were asymptomatic and recurrence-free at an average follow-up of 15 ± 5.5 months (range: 6-24). Overall, 94.5% of the 147 patients (Table 1)

stated that they were satisfied and 90.4% said they would repeat it if necessary.

DISCUSSION

The treatment of haemorrhoids has moved away from excisional techniques to less traumatic procedures[2, 3, 8-11]. Traditional haemorrhoidectomy is painful and with the development of technology alternative procedures are now available[7, 28- 31]. In general they avoid an open wound[7, 28, 32]. Thus stapled haemorrhoidopexy or Longo's procedure involves the stapled transanal circumferential "excision" of lower rectal prolapse, the excision being "translocated" to more proximal but much less sensitive rectal mucosa[7, 28, 32]. DGHAL and its variations may require the excision of redundant protrusion or cutaneous remnants, as occurred in our series and indicated by others[18]. Treatment modalities such as injection sclerotherapy, rubber band ligation and infrared photocoagulation share the principle of 'mucosal fixation' with stapled haemorrhoidopexy and DGHAL-RAR and are, to a certain extent, their clinical precursors[3, 29-31].

The pathogenesis-targeted modern management of hemorrhoids aims to interrupt the arterial blood flow and replace prolapsed haemorrhoidal tissue[3, 7-14, 16, 18]. Thomson's studies of the hemorrhoidal branches of the superior rectal artery showed an average of five branches reaching the anal cushions.[8] Based on elegant transperineal colour Doppler studies, Aigner et al demonstrated that increased caliber and arterial blood flow of the terminal branches of the artery were correlated with the appearance of haemorrhoids[11]. Even though, according to the same investigators, some transmural branches perforate the rectal wall close to the levator ani muscle,

the application of DGHAL leads to a significant reduction of the arterial flow, which is associated with the immediate shrinkage of the haemorrhoidal tissue[10,11]. Any additional more distal branches may also be controlled by additional sutures. DGHAL has been regarded with scepticism and the efficacy of the method has been attributed to the sclerosing effect of multiple suture placements, causing an additional 'pexy' effect[32].

Anopexy, mucopexy ligation and plication techniques all work through the same principle, on the sites of prolapse and not on the entire circumference of the anorectum as with circumferential stapling[19, 21-27].

The modern transanal mucopexy technique of RAR progresses from proximal to distal, suturing only the prolapsing segment of mucosa and incorporating the accompanying loose underlying submucosal layer, resulting in less chance of including large amounts of sphincter.

DGHAL-RAR notably achieves immediate reduction of the vascular component coupled with repositioning and anchoring of any distally displaced haemorrhoidal tissue. Healing occurs by fibrosis. Any residual external component may be unsatisfactory for the patient who should be made aware that skin tags may persist after DGHAL, although they may subside in the long-term[34,35]. Mucocutaneous remnants are often excised at the time of stapled haemorrhoidoppexy[34].

In the present study MMCE did not have any significant effect on the pain. It appeared therefore that the haemorrhoidopexy and not the MMCE was the main factor for pain when it occurred. It may be that improving the technique of mucopexy, for example by reducing the bulk of the incorporated tissue and avoiding the sensitive dentate line, would further reduce pain. It is however

the case that the data on analgesia in the present study were difficult to interpret, owing to the varying agents used in varying dose regimes.

It is noteworthy that significantly more ligations were required when DGHAL was applied to Grade IV haemorrhoids. This may be related to the greater number of ligations applied to this group. The requirement for more ligations at advanced grade haemorrhoids is also reflected by the significantly higher ligation numbers used in the SHP/RAR cases compared with DGHAL alone.

The present study confirms that DGHAL is a safe and effective technique[16-18, 33, 35, 36-52] (Table 1). Minimalization of anal trauma reduces adverse consequences, such as incontinence and anal stenosis. High success rates have been reported for bleeding haemorrhoids, rendering the method ideal for this symptom[16, 18, 33, 36-38, 46, 47, 49, 51]. A large proportion of our patients had long-standing, advanced and Grade IV haemorrhoids. Our success, higher than previously reported, is probably attributable to the use of SHP or RAR[17, 18, 50, 52]. A potential advantage of DGHAL over stapled haemorrhoidopexy is the lack of serious or septic complications[32], although this is not yet fully established. Avoidance of the deepest layers of the anorectal wall and the reliance on absorbable sutures instead of permanent staples may be important differences in this respect. A distally placed stitch may explain the one case of perianal fistula in our series. If bleeding persists or recurs DGHAL can be easily repeated[18, 52]. DGHAL is also applicable if another procedure for haemorrhoids had been tried before[18, 52]. It can easily be combined with other well-standardized procedures for accompanying pathologies, such as internal sphincterotomy.

The lack of a control group and the relatively small size of the patient population for such a common disease do not allow us to draw definite

conclusions for the superiority of DGHAL-RAR over other treatment modalities. It is however evident that the technique is safe and effective even for haemorrhoids of advanced grade.

TABLE 1

Parameters	Procedures			
	DGHAL	DGHAL-SHP/RAR	DGHAL-SHP	DGHAL-RAR
Number of cases (n)	87	37	27	10
Grade of hemorrhoids				
Grade III (n)	76	16	14	2
Grade IV (n)	11	21	13	8
	P<0.001			
Number of DGHAL ligations Mean $\pm$ SD* Median Range	8.7 $\pm$ 2.4 9 4-16	10.4 $\pm$ 2.5 10 4-15	10.3 $\pm$ 2.6 10 4-15	10.5 $\pm$ 2.2 10 7-14
	P<0.001			
No post-procedural pain (n)	35	0	0	0
	P<0.001			
Pain medications < 1 week (n)	49	30	21	9

	P<0.01			
Pain medications > 1 week (n)	3	7	3	1
	P<0.01			
Residual prolapse (n)	9	1	1	0
Remaining skin tags (n)	6	1	0	0
Minor bleeding (n)	7	5	3	2
Persistent bleeding (n)	1	1	1	0
Reintervention (n) **	3	1	1	0
Satisfied patients (n)	82	36	26	10

TABLE 2

Author, year	Patients (n)	Grade of haemorrhoids (n)	Follow-up (months)	Success rate	Complications (n)
Morinaga et al, 1995[16]	116			Bleeding: 95% Prolapse: 78%	Pain: 5 Bleeding: 12
Meintjes, 2000[36]	1415		5- 24	93.2%	Bleeding:8 Infection: 7 Fissure: 14 Thrombosis: 7 Early recurrence: 27
Sohn et al, 2001[37]	60	II 33, III 45, IV 22	12	Bleeding: 88.2% Prolapse: 91.8%	Thrombosis: 4 Fissure: 1 Bleeding: 4 Prolapse: 4
Arnold et al, 2002[38]	105	II 17, III74, IV 9	NR	89.6%	Bleeding: 7 Thrombosis: 3 Fissure: 2 Fistula: 1
Jongen et al, 2003[39]	133		6	80% (3 months) 61% (6 months)	Bleeding Fecal urgency Pain Submucosal hematoma (10)
Shelygin et al, 2003[40]	102	III, IV 100	12	82.6%	
Tagariello et al, 2004[41]	138			90%	
Narro, 2004[42]	281	III 115, IV 26	6- 24	84.3%	Intraoperative bleeding: 5 Fecal urgency: 3 Anal ulcer: 4 Postoperative bleeding: 2 Thrombosis: 2
Guindic et al, 2004[43]	49	II 40, III 2	4	100%	
Lienert & Ulrich, 2004[44]	248		1.5	87.7%	
Bursics et al, 2004[45]	30	I 1, II 6, III 10, IV 13	12	83.3%	Persistent pain : 2 Bleeding : 1 Fissure : 3
Ramirez et al, 2005 [17]	32	III 27, IV 5	12	88% (Grade III) 20% (Grade IV)	
Infantino et al, 2005[46]	86	II 28, III 72	4- 26	Bleeding : 90% Prolapse : 90%	Thrombosis : 1 Urinary retention : 1
Felice et al, 2005[47]	68		11	Bleeding : 91% Prolapse : 94%	Bleeding : 3 Thrombosis : 1
Greenberg et al, 2006[48]	100	II, III 100	6	94%	
Sheyer et al, 2006[18]	308	II 89, III 192, IV 27		Bleeding : 96% Prolapse: 75%	Bleeding: 15 Thrombosis: 9 Defecation pain: 5 Fissure: 4 Stool retention: 1 Urinaryy retention: 1 Fistula: 1 Proctitis: 1
De Vries et al, 2007[49]	110	II 42, III 68	9	88%	Persistent prolapse : 9 Bleeding : 1 Fissure : 1

					Urinary retention : 1
Witte & Klaase, 2007[50]	61		3- 11	Symptom-free: 75% Improved : 12%	Bleeding : 5 Urinary retention : 2 Severe pain : 1
Dal Monte et al, 2007[33]	330	II 138, III 162, IV 30	46	Bleeding: 92.5% Prolapse: 92%	Bleeding: 7 Thrombosis: 5 Submucosal hematoma: 4 Urinary retention: 2 Fissure: 2
Abdeldaim et al, 2007[51]	35		18	Bleeding: 85% Prolapse: 81%	
Dorn & Mory,2007[52]	200	I 84, II 76, III 40	60	80.5% (6 months) 79% (2 years) 73.5% (5 years)	Submucosal hematoma: 21 Intraoperative bleeding: 2 Postoperative bleeding: 10 Thrombosis: 4 Fissure: 3
Faucheron & Gagner, 2008[35]	100	II 1, III 78, IV 21	36	88%	Persistent pain: 5 Bleeding : 4 Thrombosis : 3 Fissure : 2 Dyschezia : 1

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LEGENDS

Table 1: The results of Doppler-guided haemorrhoidal artery ligation (DGHAL) alone and combined with suture haemorrhoidopexy (SHP) and rectoanal repair (RAR) in 124 patients. Only statistical significant comparisons are indicated with *p* values. * SD: Standard Deviation, ** Reintervention refers to the two cases with residual prolapse and the two cases with persistent bleeding that required a second haemorrhoid procedure

Table 2: Results of Doppler-guided haemorrhoidal artery ligation reported in the literature

Figure1: Operative view of Doppler-guided haemorrhoidal artery ligation (upper left), suture haemorrhoidopexy (upper right), rectoanal repair (lower left) and schematic diagram of the “figure-of-eight” stitch for haemorrhoidal artery ligation at the left and of the continuous “running” suture for haemorrhoidopexy at the right (lower right)

Figure 2: Rectoanal repair in a patient with Grade IV haemorrhoids: Change of the operating window of the proctoscope from the “ligating” to the “pexy” position allows the prolapsing tissue to come into view through the window (upper left). A running suture with 3-5 stitches is applied to surround the prolapse (upper right). The most distal stitch is tied to the most cranial stitch in order to lift the prolapse (lower left). Final result after completion of rectoanal repair (lower right)

Figure 3: Patients, grades of haemorrhoids and procedures performed. DGHAL: Doppler-guided haemorrhoidal artery ligation, SHP: Suture haemorrhoidopexy, RAR: Rectoanal repair, MMCE: Minimal (muco-) cutaneous excision

Figure 4: Haemorrhoidopexy was required more often at grade IV haemorrhoids. HAL: Doppler-guided haemorrhoidal artery ligation, HP: Suture haemorrhoidopexy, RAR: Rectoanal repair


DOPPLER-GUIDED
HEMORRHOIDAL ARTERY
LIGATION
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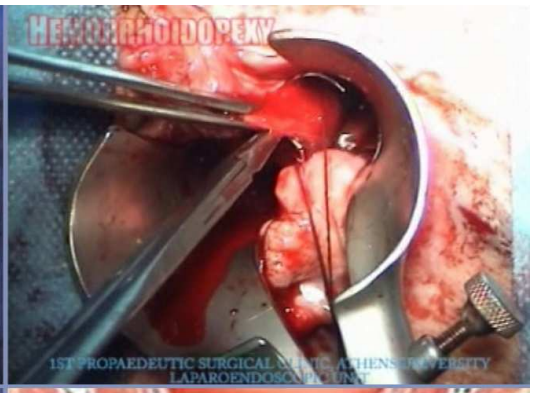
LAPAROENDOSCOPIC UNIT


HEMORRHOIDOPEXY


RECTO ANAL
REPAIR
A.M.I...
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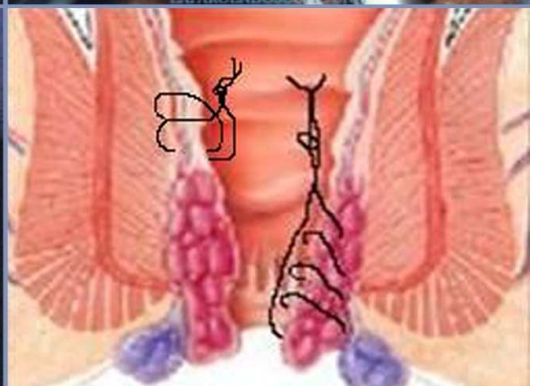

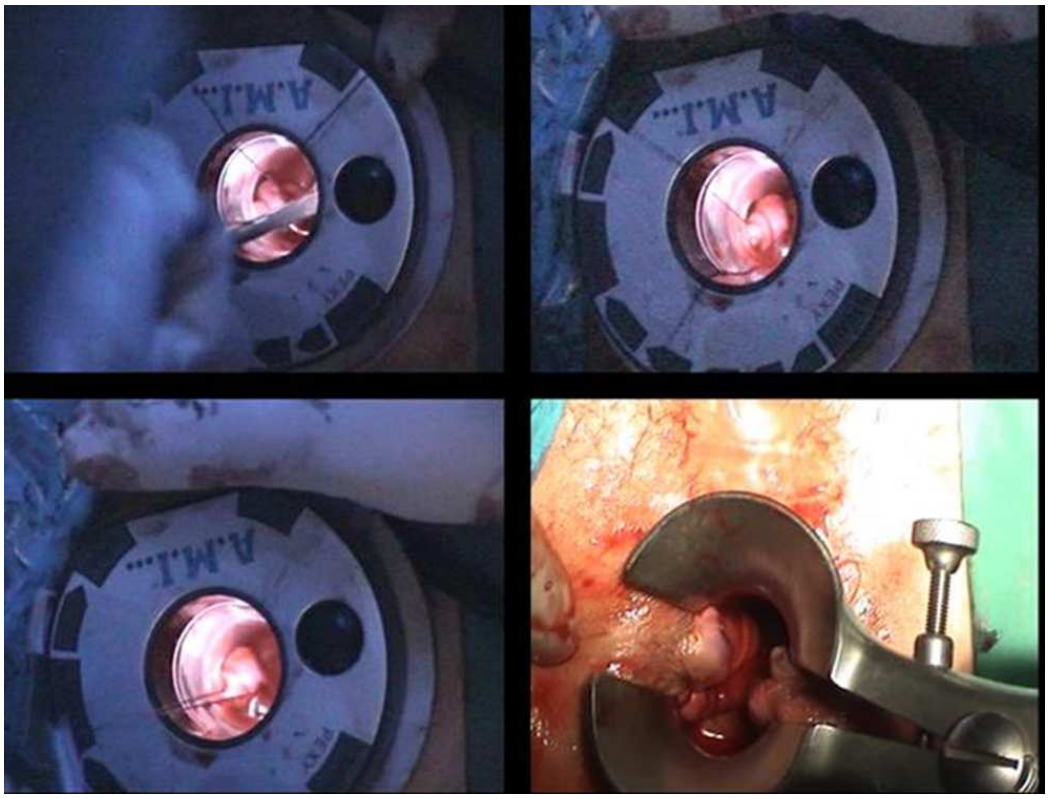
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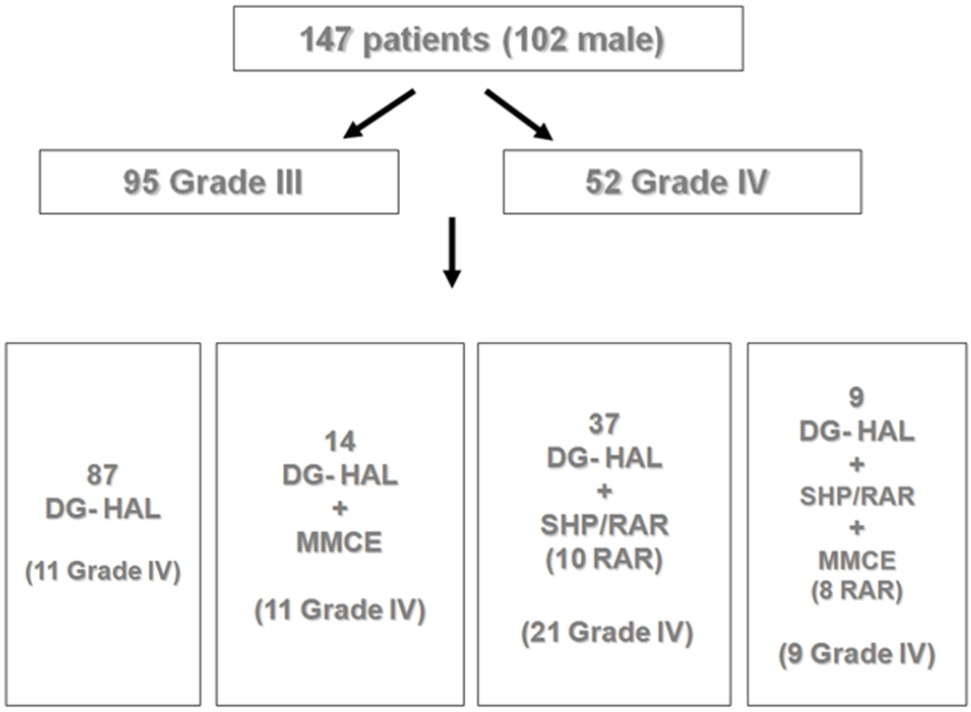
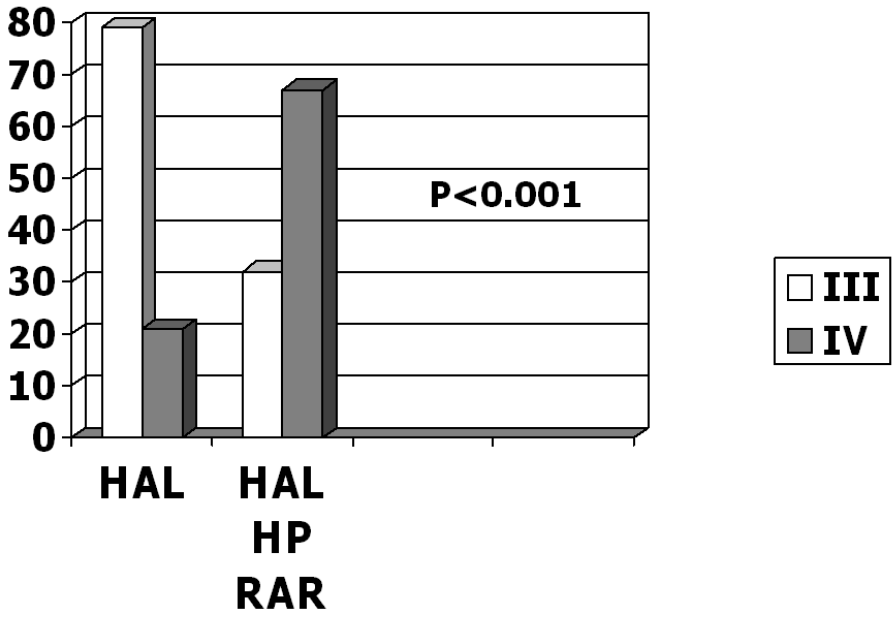

147 patients (102 male)
95 Grade III
52 Grade IV
87
DG- HAL
(11 Grade IV)
14
DG- HAL
+
MMCE
(11 Grade IV)
37
DG- HAL
+
SHP/RAR
(10 RAR)
(21 Grade IV)
9
DG- HAL
+
SHP/RAR
+
MMCE
(8 RAR)
(9 Grade IV)


80
70
60
50
40
30
20
10
0
P<0.001
HAL
HAL HP RAR
III
IV