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Editorial
Twenty five years

Mark Skues, Editor-in-Chief

This edition of the *Journal* marks a milestone in the history of 'Ambulatory Surgery' with our 25th anniversary. First published in 1994, the *Journal* has been a repository of seminal papers on every aspect of ambulatory care across the world. It is my pleasure to thank all of the authors who have contributed to publication, as well as my predecessor editors who managed submissions promptly and seamlessly. In the last quarter century, the world of ambulatory care has altered dramatically with increasing numbers of countries adapting practice to accommodate shorter durations of stay, and thereby, reduced costs of care. Long may it continue.

This issue contains four submissions evaluating the results of treatment of haemorrhoidal disease using arterial ligation, an evaluation of which surgeons should perform laparoscopic cholecystectomy, consideration of ambulatory surgery for orthopaedic patients in the United States, and a brief report on the potential use of music therapy.

De Vos and colleagues from Belgium evaluated the outcomes of 274 haemorrhoidal artery ligations (HAL) over a 10 year period, of which, nearly 75% were ambulatory procedures. Given the higher potential of post-operative prolapse, the authors combined concomitant rectal mucopexy that functions to lift and secure protruding haemorrhoids. They found high patient satisfaction with a reduction in symptomatology, but over 40% of patients needed further treatment.

An English study evaluates performance of laparoscopic cholecystectomy enquiring whether the operations should be limited to surgeons who have sufficient experience. Recommendations are already in force suggesting they should be restrictions to surgeons who perform more than 40 procedures per year, and the evidence accrued would suggest that open conversions, daycase and reoperation rates were higher when the operation was performed by individuals with greater experience.

Uppal has studied the economic advantages of orthopaedic surgery in surgical centres compared with hospital outpatients, comparing risk of surgical site infection, duration of procedure and patient satisfaction. He found that all the cited parameters were better in surgical centres, leading to the premise that financial involvement and/or ownership by physicians may have an impact.

The fourth paper is a brief evaluation of the benefits of music therapy for ambulatory surgery patients where the authors measured anxiety in a control group and patients subjected to music of their choice through the surgical procedure. Music seemed to reduce anxiety in patients, though one hopes that their choice was better than that of some surgeons I have had the delight of working with!

And finally, a brief note to once again recommend the forthcoming congress in Porto in May this year. The next edition will be a collection of the abstracts submitted to the Congress, that we will all have the pleasure of hearing and viewing. I hope to see you there.

Mark Skues
Editor-in-Chief

A retrospective, single-centre analysis on Haemorrhoidal Artery Ligation (HAL) and Recto-Anal Repair (RAR) after ten years

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Abstract

Introduction: Haemorrhoidal Artery Ligation (HAL) +/- Recto-Anal Repair (RAR) is a minimally invasive surgical technique for all grades of hemorrhoidal disease. This paper reports on the results after ten years of follow-up.

Methods: This retrospective study analyzed the outcomes of 274 consecutive HAL or HALRAR procedures between January 2004 and August 2014, at Sint-Lucas General Hospital in Ghent, Belgium. Data was collected through a questionnaire and the patient records. All data was analyzed with SPSS 24.0.

Results: The initial symptomatology was discomfort in daily life, anal blood loss, anal pain and hemorrhoidal prolapse. Before seeking medical treatment, 61.1% were symptomatic for years. Patients were treated by HAL or HALRAR. During a HAL procedure, a mean of 5 sutures were placed. For RAR, a mean of 2 mucopexies were performed. The majority (74.8%) was treated on a day-clinic basis. Mean Visual Analog Scale (VAS) for postoperative pain is 5.28. The postoperative complication rate was 11.3%, most frequently anal pain (3.6%), hemorrhoidal thrombosis (3.3%) and urinary retention (2.6%). Symptoms of hemorrhoidal disease decreased significantly after HAL or HALRAR, but 44.4% of patients needed further treatment. Satisfaction after HAL or HALRAR was 84.4%.

Conclusion: These long-term results after HALRAR show a significant decrease in symptomatology and a high patient satisfaction but confirmed concerns about high recurrence rates. More prospective randomized trials are needed to evaluate long term results compared to other surgical techniques.

Keywords: Haemorrhoidal Artery Ligation, Recto-Anal Repair, Follow up.

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Introduction

Haemorrhoidal disease is the most common disease of the rectum. Usually, patients do not seek early treatment given the nature of the disease but the prevalence is estimated to range between 4.4% and 36.4% [1]. Approximately 10-20% of patients will require surgery [2].

Haemorrhoids are a physiological plexus of veins located between the lamina muscularis mucosa and sphincter muscle structures and consists of a superior (inner) and inferior (external) part divided by the dentate line. Because of arterial shunts and an extension of veins, this plexus becomes enlarged and plays an important role in "fine continence" of the anal canal [1,2].

Today, haemorrhoidal disease is considered as a typical "civilization" disease, and nutrition, hygiene, and constitution, plays an important role in its development. The main pathogenetic cause for haemorrhoidal disease is increased intraluminal blood pressure of the distal rectum. This results in an imbalance between arterial inflow and venous return. Reasons for the increase in intraluminal blood pressure are multifactorial and most probably individually different [3]. Fibre-free food, high tonus rates of the sphincter apparatus, stress and anatomic, physiologic and hereditary factors are currently considered possible causes.

Enlargement and displacement of haemorrhoids typically presents with symptoms such as bleeding, pruritus, prolapse, sensation of incomplete evacuation, soiling, recurrent thrombosis of piles, etc. (which are bothersome and difficult to attenuate) [4, 1]. However, the grade of prolapse and haemorrhoidal symptoms are often poorly correlated [5]

The current well-accepted grading of haemorrhoids, also known as the Goligher's classification [6], is based on the morphology of the piles: grade I = enlarged haemorrhoidal plexus, without prolapse, but with bleeding; grade II = prolapsing piles with spontaneous repositioning of piles; grade III = manual repositioning of piles possible and required; grade IVa = prolapsing piles with acute incarceration and thrombosis; and grade IVb = repositioning of piles impossible, fibrotic prolapse occurs.

Initial treatment for grade 1, 2 (and 3) haemorrhoids is conservative management, meaning dietary and lifestyle modifications for example fibre rich diet and better defecation discipline [7], followed by medical treatment with local application of ointments or oral medication or minimally invasive treatment like sclerotherapy, photocoagulation and cryotherapy.

An outpatient treatment that seems to be more effective for both bleeding and prolapse is rubber banding. A meta-analysis [8] has shown that rubber banding is more effective in both the short and long term compared to photocoagulation. Overall, it appears that between 60-80% of patients who have undergone banding are satisfied with the outcome [8-11].

The disadvantages of all these methods include necessity of several sessions for successful results, a relatively high recurrence rate, impaired sense of well-being caused by foreign-body sensation or pain (10% in the case of rubber-band ligation), occurrence of necrosis, or allergic reactions to the sclerosant [1].

If symptoms prevail, there is a wide range of surgical treatment modalities.

A variety of surgical procedures are now available but no single technique has been universally accepted as superior. This is because the indication for treatment is not only based on the gradation of the haemorrhoids but mainly on the subjective severity of symptoms among patients and quality of life. While the choice of treatment

is based on the gradation of the haemorrhoids, local experience, surgeon's preference and availability of specialized equipment [7,12,13].

Conventional surgical haemorrhoidectomy according to Milligan and Morgan [14], the one modified by Parks [15] or according to Ferguson [16] represent the most effective treatments of persistent grade III and IV haemorrhoidal disease. These surgical interventions usually require several days of inpatient treatment and may lead to severe postoperative pain, severe enough to eliminate 75% of patients from professional life and normal daily activities for a considerable time [17,18]. Other complications are sphincter dysfunction (in up to 25% of patients), postoperative bleeding (in 5-15% of patients) and the risk of a recurrence of the disease, which reaches 30%. Also, an operative haemorrhoidectomy may be contraindicated for some patients (e.g., those suffering from incontinence) [17].

As patients are often reluctant to undergo painful treatments for benign conditions, management of haemorrhoidal disease has evolved to develop effective but less invasive treatment with the aim of reducing the risk of anatomical alterations and dysfunction of the anal canal, minimizing postoperative pain and providing relief of symptoms [12].

Implementing any type of surgical technique, it must be remembered that the plexus haemorrhoidalis (corpus cavernosum recti) plays an important role within the anal sphincter apparatus and that there is a fine line between successful treatment and the risk of damaging the anal sphincter.

Longo's [19] technique (stapled haemorrhoidopexy) is a less invasive surgical technique that consists of the resection of the mucosal prolapse with the use of a circular stapler. Possible severe complications are rectal anastomotic leakages with pelvic sepsis, rectal obstruction, perforation, recto-vaginal fistula, sphincter damage, retroperitoneal hematoma and Fournier gangrene. Complication rates vary between 6 – 31% [20,21].

The last two decades haemorrhoidal artery ligation (HAL), first described by Morinaga in 1995 [22], has become universally accepted for the treatment of haemorrhoids. The rationale for this procedure is based on the assumption that arterial blood flow is mainly responsible for the enlargement of the haemorrhoidal plexus due to the absence of capillary interposition between the arterial and venous systems within the anal canal. The intraluminal arteries, terminal branches of the superior rectal arteries, are located 2 cm proximal to the dentate line and ligated by means of a special proctoscope, which contains an integrated Doppler transducer and a lateral ligation window. The Doppler transducer is located distal to the lateral ligation window. With the applied frequency of 8.2Mhz and an introduction angle of approximately 60°, a screening depth of approximately 7mm is provided. Because the arteries carrying the blood inflow are ligated, the internal pressure of the plexus haemorrhoidalis has decreased, and the typical symptoms of haemorrhoids disappear.

Several studies have reported that (Doppler Guided) Haemorrhoidal Artery Ligation (HAL) is an effective and safe alternative to operative haemorrhoidectomy with the advantages of a short learning curve, no risk of postoperative faecal incontinence, less postoperative pain and a short recovery period [1,23-30]. The success rate observed 1 year postoperatively is 89%, and 73% 5 years postoperatively and recurrence seems to be the greatest during the first year after HAL [1,31-33]. It seems especially effective in grade 2 and 3 haemorrhoids [1, 30, 33, 34]. It might be a good alternative to conventional haemorrhoidectomy but the rates of effectiveness and patient satisfaction after long-term follow-up are still unknown and, currently, no large, prospective, randomized, controlled trial has been published [1,17,28].

Clinical experience has revealed that it can be difficult to silence all Doppler signals during the procedure, even after application of multiple ligations [1]. Nevertheless patients may experience relief of their complaints. In literature, it is assumed that on average 6 to 8 ligations would suffice to achieve complaint reduction, while in a recent anatomical study it was shown that the distal rectum is provided by more than 6 twisting arteries [1,9,35,36]. This discrepancy between peroperative experiences and clinical outcome and the insight into the anatomical configuration of the distal rectum raises the question in what way the proctoscope and Doppler transducer is intervening in the anatomical configuration and whether there might be another mechanism that could explain the beneficial effect of the HALRAR procedure. The findings of Jaap-Peter Schuurman [36] confirm that the haemorrhoidal artery ligation procedure reduces signs and symptoms of haemorrhoidal disease. But also claims that the Doppler transducer does not contribute to this beneficial effect and could be omitted during the ligation procedure. This topic remains contradictory [37]. HAL alone has proven being less effective in the case of grade III and IV haemorrhoids [30,35,38].

Several studies have mentioned the poor ability of the HAL technique to control prolapse [39,40]. To address this shortcoming, the technique was modified at the end of 2005 [40]. A new proctoscope was designed to allow a combination of classical HAL with a transanal rectal mucopexy that serves to lift and secure the protruding haemorrhoids [41-43]. The term Recto-Anal Repair (RAR) has been used to designate either the combined procedure [44,45], or as in the present report and others, the mucopexy alone [44-46].

In this study we analyzed long-term results after HAL or HALRAR procedures through information gathered from a questionnaire and from the patient records.

Methods

This study evaluates all patients who underwent Haemorrhoidal Artery Ligation (HAL) with or without Recto-Anal Repair (RAR) between January 2004 and August 2014 at Sint-Lucas General Hospital in Ghent, Belgium. The study was approved by the local Ethical Committee. Initially 365 patients were selected. After careful analysis of all the individual cases, 274 patients were included in the study. Inclusion criteria were grade I – grade IV haemorrhoidal disease and age between 18 and 75 yrs. Exclusion criteria were co-existent anal pathologies, such as anal fistula, anal fissure and perineal abscess; Inflammatory Bowel Disease (IBD), a history of colorectal tumors; portal hypertension; neurologic diseases that affect the colonic motility and/or the anal sphincter and pregnancy (Figure 1) (near here). In our protocol, patients previously treated for haemorrhoidal disease were not excluded from the study as this would reduce the patient population greatly and the possibility to perform the procedure after previous treatments is considered an advantage.

Patients characteristics, preoperative, peroperative and postoperative information (Table 1) was gathered trough patient records and by a questionnaire that was drafted and sent (by post or by e-mail) to the patients after obtaining informed consent by phone. The questionnaire was created after thorough literature research for previously reported outcomes after Haemorrhoidal Artery Ligation (HAL) and Recto-Anal Repair (RAR).

Operative technique

All procedures were performed by one surgeon, Dr T. Onghena at the department of surgery in Sint-Lucas general hospital in Ghent, Belgium. Preoperatively, no bowel preparation and no antibiotic

Figure 1 Flowchart of patient enrolment in the study.

prophylaxis was given. The procedure was performed with local, spinal or general anesthesia according to the preference of the patient and anaesthesiologist. The patient was positioned in the lithotomy position. The perineal skin region was cleaned and the patient was covered with sterile draping. The Haemorrhoidal Artery Ligation (HAL) and Recto-Anal Repair (RAR) was performed with HAL-Doppler II System (A.M.I. - Agency for Medical Innovations, Austria) and the accompanying HAL needle holder, knot pusher and suture (which is a 5/8 circle needle with synthetic, absorbable, 2/0 suture filament). The anal canal was gently dilated to a width of two fingers. Before the anoscope is inserted, defaecation was mimicked by inserting two surgical gauzes into the anus and pulling them back out, thereby visualizing prolapse of the haemorrhoidal piles. The anoscope was lubricated and inserted through the anal canal to a depth of 6-7cm from the anal margin and 2-3cm above the dentate line. The doppler was set at 6'o clock in the lithotomy position and proceeded clockwise. The Doppler system was activated and the anoscope was slowly rotated and tilted to search for all the haemorrhoidal arteries (branches of the superior rectal artery). After each quadrant the anoscope was pulled out and reinserted to prevent further rotation of the anal mucosa. A figure-of-eight suture was conducted at the sites where the doppler sound is most prominent and the accuracy of the ligation is confirmed by the loss of the Doppler signal afterwards. The procedure was repeated twice to make sure no arteries were left untied. After finishing the Haemorrhoidal Artery Ligation (HAL) procedure, 'the defaecation mimicking test' was repeated with special attention to previous sites of haemorrhoidal prolapse. Where residual prolapse was present, Recto-Anal Repair (RAR) was performed. The anoscope was again inserted and a longitudinal running plication suture was placed (0.5cm between each step) through the enlarging slot in the anoscope. This was executed from proximal to distal under direct vision. When the margo analis was visualized the anoscope was retracted and the suture was tied. The mucopexy could be felt while tying the suture. This procedure was then repeated for every prolapsing haemorrhoidal pile. Haemostasis was controlled and if necessary a Spongostan Anal 8cmx3cm (Ethicon, Germany) was used. All patients received a pudendal block at the end of the procedure using 20ml of 0.75% Ropivacaine.

Statistical analysis

All data was analyzed using the statistical software SPSS 24.0. The categorical (ordinal) data was analyzed using the Wilcoxon matched pairs signed ranks test for two dependent samples, the Mann-Whitney U test for two independent samples and the Chi-square test for categorical data. These are non-parametric test as data was not normally distributed. The confidence level used is 95% (significance level $p<0.05$).

Results

All the patients included in the study (n=274) were contacted by phone. After gaining informed consent, the questionnaire was sent by post or e-mail. One hundred and fifty-five patients completed the questionnaire, this resulted in a response rate of 56.6%. From those patients, who could not be contacted, information from the patient record was used.

Patient characteristics

The patients' mean age was 51 yrs (25-74 yrs).

There were 159 male participants (58%) and 115 females (42%), which resulted in a male:female ratio of 1.38.

Patient history

The grade of haemorrhoidal disease was gathered from the patient records. Most participants suffered from grade II haemorrhoidal disease (45.3%), followed by grade III (27.4%), grade I (22.6%) and grade IV (4.0%).

The patients who participated in the study were asked to describe their initial complaints.

Table I Patients characteristics, preoperative, perioperative and postoperative variables.

Patient characteristics	**Descriptor**
Date of birth	DD.MM.YYYY
Age	18 – 70 yrs
Gender	M/F
Preoperative variables	
Grade of hemorrhoidal disease	Goligher's classification, grade I – IV [6]
Initial symptoms	
Discomfort in daily life	Never
Anal blood loss	Seldom
Anal pain	Sometimes
Anal itching	Often
Anal discharge	Daily
Hemorrhoidal prolapse	
Unpleasant odour	
Constipation	
Fecal incontincence	
Tenesmus	
Hemorrhoidal thrombosis	
Duration of complaints	
Previous treatments	
Conservative (high fiber diet, hygiene, etc.)	Y/N
Medical (ointment, laxatives, venotropic drug, etc.)	Y/N
Minimally invasive treatment	
Rubber band ligation	Y/N
Photocoagulation	Y/N
Sclerotherapy	Y/N
Surgery	
Haemorrhoidectomy	Y/N
Perioperative variables	
Date of surgery	DD.MM.YYYY
Type of surgery	HAL, HALRAR, RAR
Anaesthesia	Local, Spinal, General
Duration of surgery	Minutes
Peroperative blood loss	mL
Hemorroidal Artery Ligation – Sutures	Total amount and according to the position of the suture
Recto-Anal Repair – Mucopexies	Total amount and according to the position of the suture
(Perioperative complications)	(None were recorded)
Postoperative variables	
Hospital days	Days
Pain after Surgery	VAS scale (0-10)

Early postoperative complications	
Anal pain	Y/N
Anal blood loss	Y/N
Hemorrhoidal thrombosis	Y/N
Proctitis	Y/N
Anal fissure	Y/N
Anal fistula	Y/N
Fecal incontinence	Y/N
Urinary tract infection	Y/N
Urinary retention	Y/N
Follow-up after one month	
Discomfort in daily life	Never, seldom, sometimes, often, daily
Anal blood loss	
Anal pain	
Anal itching	
Anal discharge	
Hemorrhoidal prolapse	
Unpleasant odour	
Constipation	
Fecal incontincence	
Tenesmus	
Hemorrhoidal thrombosis	
Residual perianal tags	
Additional treatment	
Conservative (high fiber diet, hygiene, etc.)	Y/N
Medical (ointment, laxatives, venotropic drug, etc.)	Y/N
Minimally invasive	
Rubber band ligation	Y/N
Photocoagulation	Y/N
Sclerotherapy	Y/N
Surgery	
Hemorrhoidal Artery Ligation (HAL) / Recto-Anal Repair (RAR)	Y/N
Hemorrhoidectomy	Y/N
Satisfaction after surgery	Not satisfied, Displeased, Neutral, Satisfied,Very satisfied
If necessary, would you choose the HALRAR surgery again?	Y/N

Never
Seldom = 1-3 times a month
Sometimes = once a week
Often = more then once a week
Daily

The majority of patients had discomfort in daily life, anal blood loss, anal pain and haemorrhoidal prolapse. These four seem to be the cardinal symptoms of haemorrhoidal disease in this group of patients and was present on 'a weekly basis' or 'often'. Anal itching was a more variable symptom, but is still apparent 'more than once a week' in 23.9% of all cases. Anal discharge, unpleasant odour, constipation, fecal incontinence and tenesmus were less frequent symptoms, only seldomly present in a minority of patients. The questionnaire also showed that 61.1% of all patients had one or multiple episodes of haemorrhoidal thrombosis.

When asked about the duration of their complaints, it seemed most patients faced years of symptomatic haemorrhoidal disease before seeking medical treatment. In this study 86/170 patients or 50.6%. Very few people were treated instantly, 9/170 or 5.3%. The majority of patients, 127/172 or 73.8%, already received some sort of treatment of their haemorrhoids. Mostly medical treatment, 87/159 or 54.7%, which means application of ointments, the use of laxatives, etc. This was followed by minimally invasive sclerotherapy, 45/166 or 27.1%, conservative therapy (high-fiber diet, hygiene, etc), 31/159 or 20.1%, minimally invasive rubber band ligation, 27/160 or 16.9%, surgical haemorrhoidectomy, 23/161 or 14.3% and minimally invasive photocoagulation, 20/162 or 12.3%.

Surgery

The patients included in this study either had Haemorrhoidal Artery Ligation (HAL) alone, either in combination with Recto-Anal Repair (RAR). 130 out of 274 patients were treated by HAL, this is 46.4%. The other 143 patients or 52.2% (1 missing, 0.4%) got both (HALRAR) because of haemorrhoidal prolapse. In the majority of patients, 77.0%, the procedure was performed under general anesthesia , 2.6% got spinal anesthesia and 5.5% received only local anesthesia. In 40 cases the type of anesthesia was not mentioned in the patient record.

In 195 cases the duration of the surgery was listed. The mean operating time was 44.5 minutes (20-80 minutes). Peroperative blood loss was estimated in 195 cases and can be considered negligible.

HAL

Of all the patients included (N=274), the total amount of HAL sutures was recorded in 259 cases and further details about the location of the sutures was found in 231 cases. A minimum of 2 sutures and a maximum of 8 were placed. The mean amount of sutures was 5. In Figure 2 the distribution of the sutures is visualized.

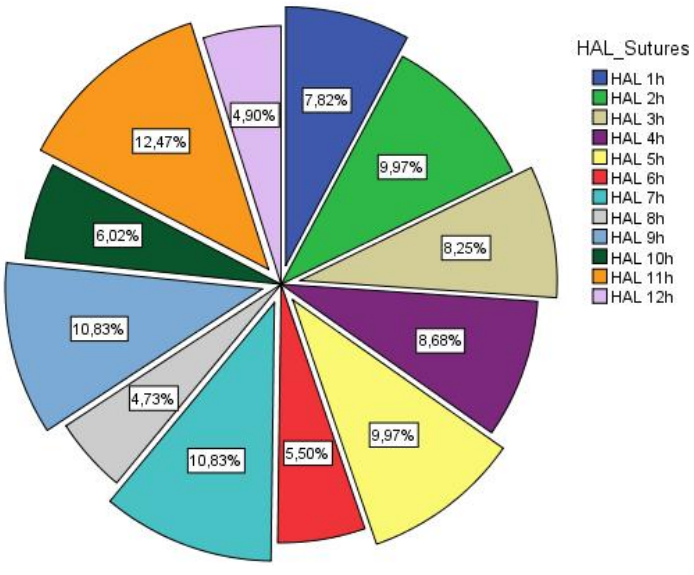

Figure 2 Total of HAL sutures placed per hour.

RAR

One hundred forty-eight patients needed an additional RAR. The total amount of mucopexies was recorded in 142 cases and further details about the location of the sutures was found in 132 cases. A minimum of 1 RAR mucopexy and a maximum of 3 were placed, with a mean of 2 mucopexies. In Figure 3 the distribution of the mucopexies is visualized.

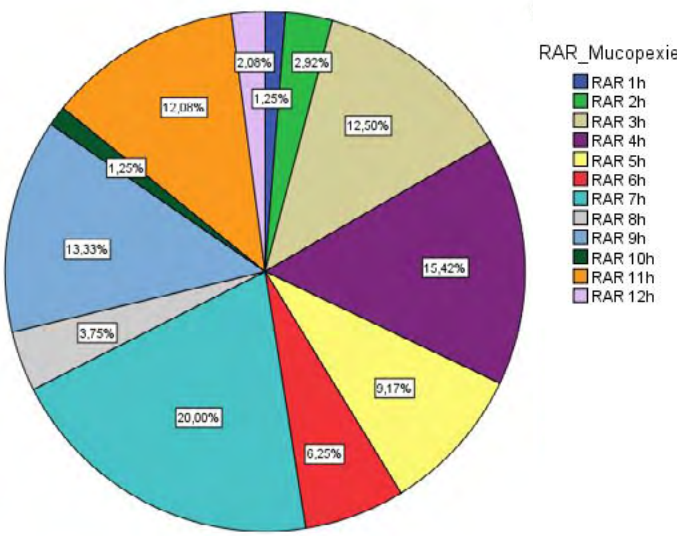

Figure 3 Total of RAR mucopexies placed per hour.

Postoperative care

Patients stayed in the hospital during minimum one day and maximum 4 days. The 4-day hospitalization was needed for only one patient, who suffered from postoperative haemorrhoidal thrombosis. The mean hospital stay was 1.30 days. Most patients, 205/274 or 74.82%, were treated on a day-clinic basis.

Postoperative pain was evaluated by the Visual Analogue Scale (VAS) pain score and ranges between 0 and 10. Zero equals no pain and 10 unbearable pain. Analysis showed a wide distribution of pain perception among patients postoperatively, with a mean VAS pain score of 5.28 (Figure 4). Statistical analysis with the use of the Mann-Whitney U test was performed to determine if there is a statistical difference between pain after HAL and pain after HALRAR. The result was statistically significant, with a higher pain score for HALRAR ($p<0.05$) (Figure 5). The mean VAS pain score after HAL is 4.17 and the mean VAS pain score for HALRAR is 6.06.

Patients were asked if they had any postoperative complications in the first month after surgery. 93/274 or 33.9%

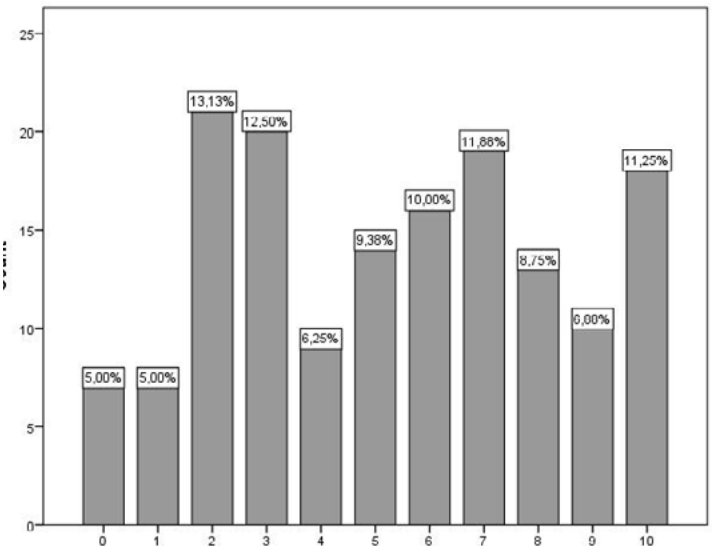

Figure 4 Postoperative pain by Visual Analog Scale (VAS-score).

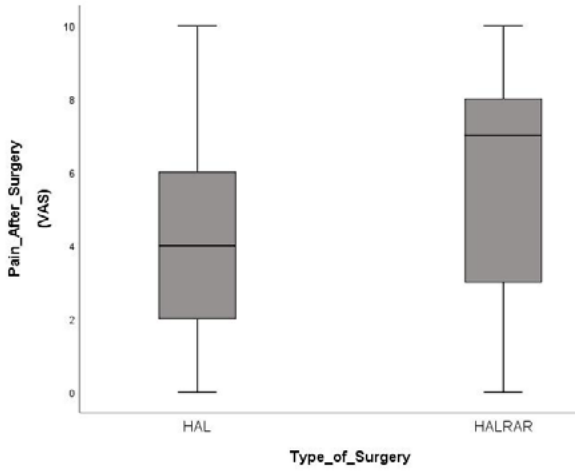

Figure 5 Difference in pain (measured by Visual Analog Scale (VAS-score) between HAL and HALRAR.

answered 'yes'. They were asked to specify their postoperative complication. Those with the highest prevalence were anal pain, 54/274 or 19.7%, followed by anal blood loss, 39/274 or 14.2%, and haemorrhoidal thrombosis, 20/274 or 7.3%. These three complications already accounted for 41.2% of all early postoperative complications according to the patients. Less frequently, patients experienced an anal fissure, 12/274 or 4.4%, urinary retention, 11/274 or 4.0%, proctitis, 9/274 or 3.3%, fecal incontinence, 8/274 or 2.9%, anal fistula, 5/274 or 1.8% and urinary tract infection, 5/274 or 1.8%.

Because the questionnaires gave us an exceptionally high number of postoperative complications and it seemed that the answers in the questionnaire did not match the postoperative information in the patient record, we compared them.

Based on the patient record alone, only 31/274 patients, or 11.3%, suffered a postoperative complication. The most abundant postoperative complications was anal pain, 10/274 or 3.6%, followed by haemorrhoidal thrombosis, 10/274 or 3.3%, urinary retention, 4/274 or 2.6%, anal fissure, 4/274 or 1.5%, anal blood loss, 2/274 or 0.7%, urinary tract infection, 1/274 or 0.4%, and proctitis, 1/274 or 0.4%. There was no report of postoperative fecal incontinence or anal fistula.

These results show a much lower postoperative complication rate but also a different ranking order.

We analyzed the data by using the Wilcoxon signed rank test ($p<0.05$)). Overall there is a significant reduction in postoperative complications between the answers from the questionnaire and the patient record ($p<0.05$). After analyzing the different possible postoperative complications, there is a significant difference for anal pain, anal blood loss, haemorrhoidal thrombosis, proctitis and fecal incontinence. But not for urinary retention, urinary tract infection, anal fistula and anal fissure. An overview can be seen in Figure 6.

Of all patients treated, 235/274 or 85.8%, were questioned after one month. At this point they were asked to formulate their residual complaints. In all the categories the majority of patients never complained about discomfort in daily life, 70/154 or 45.5%, anal blood loss, 90/147 or 61.2%, anal itching, 93/148 or 62.8%, anal pain, 87/150 or 58.0%, anal discharge, 107/146 or 73.3%, haemorrhoidal prolapsed 79/151 or 52.3%, unpleasant odour, 129/154 or 83.8%, constipation, 91/155 or 58.7%,faecal incontinence, 135/153 or 88.2%, tenesmus, 115/156 or 73.7% and haemorrhoidal thrombosis, 113/161 or 70.2%, after surgery. Still 31/160 or 19.4% experienced one or multiple haemorrhoidal thromboses after HAL or HALRAR. An additional category was

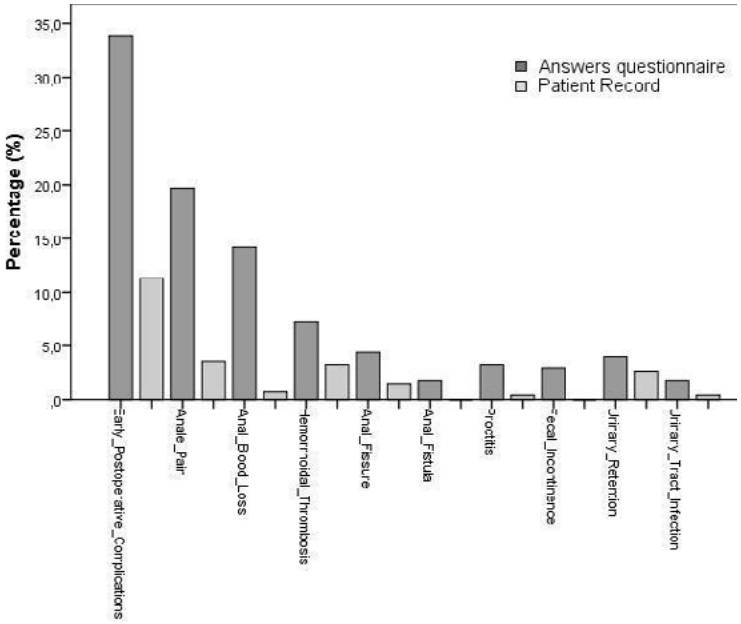

Figure 6 Early Postoperative Complications – answers from the questionnaire compared to patient record.

added named 'residual perianal tags'. Ninety-six out of 152 or 63.2% never complained about residual perianal tags, on the other hand 24/152 or 15.8% did on a daily basis.

We analyzed the difference between initial and postoperative symptoms by using the Wilcoxon signed rank test ($p<0.05$). Symptoms are all significantly less apparent after HAL or HALRAR surgery except for fecal incontinence ($p=0.505$), which has a similar prevalence pre- and postoperatively (Figure 7).

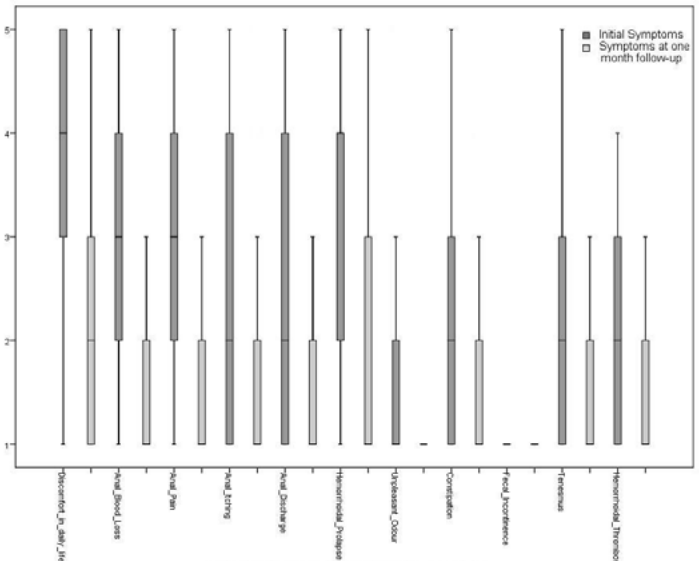

Figure 7 Comparison between initial symptomatology and symptoms one month after surgery.

We also analyzed the data grouped by grade of haemorrhoidal disease. As reported earlier, grade II haemorrhoidal disease was most and grade IV haemorrhoidal disease least abundant. The Wilcoxon signed rank test shows a significant difference in almost all symptoms ($p<0.05$) in grade I to grade III. Grade IV haemorrhoidal disease could not show any significant difference in symptomatology pre- and postoperatively. There are only 11 patients who presented with grade IV haemorrhoidal disease. There is no significant difference in 'unpleasant odour' and 'haemorrhoidal thrombosis' in grade III haemorrhoidal disease. There is no significant difference in 'tenesmus' in grade I haemorrhoidal disease.

After their initial HAL or HALRAR surgery, 71/161 or 44.1%, needed additional treatment for their haemorrhoidal disease. Most of them medical treatment, 36/153 or 23.5%, followed by redo HAL or HALRAR surgery, 22/153 or 14.4%, conservative treatment, 15/153 or 9.8%, haemorrhoidectomy, 14/153 or 9.2%, photocoagulation, 8/153 or 5.2%, rubber band ligation, 7/153 or 4.6%, or sclerotherapy, 4/153 or 2.6%. There was no significant difference in the need for additional treatment after HAL or HALRAR surgery ($p<0.05$), using the Mann-Whitney U test for two independent samples.

Satisfaction after HAL or HALRAR was also evaluated. The majority of patients, 102/161 or 84.4%, are neutral, satisfied or very satisfied with the results after surgery. 25/161 or 15.5% are displeased or not satisfied.

When asked if they would consider the same surgery when necessary, the majority said yes, 118/160 or 73.8%. Twenty-eight out of 160 or 17.5%, 'don't know' if they would choose the same surgery and 14/160 or 8.8% would not consider it. There is no significant difference in satisfaction after surgery or redo surgery between HAL or HALRAR. This was evaluated by using the Chi-square test ($p<0.05$) (Figures 8 & 9).

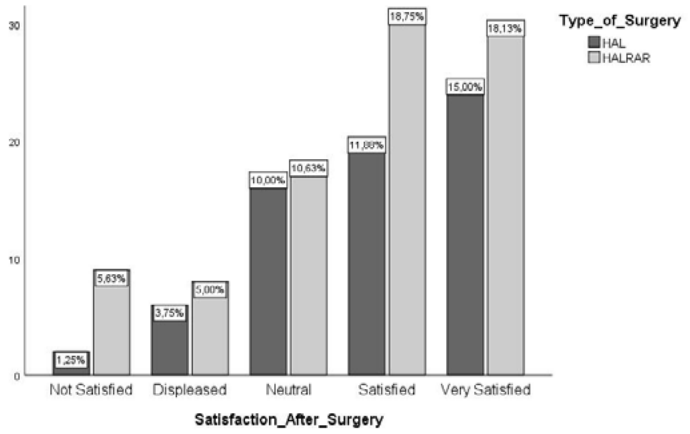

Figure 8 Satisfaction after surgery results compared between HAL and HALRAR.

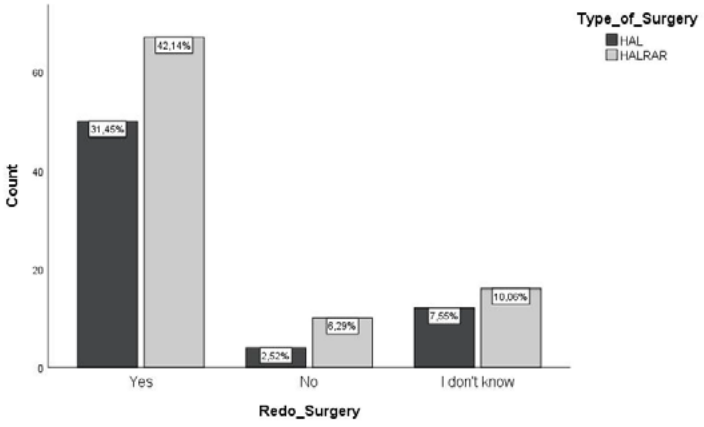

Figure 9 Answers to the question: If necessary, would you choose the HALRAR surgery again? Comparison between HAL and HALRAR.

Discussion

Since the introduction of Haemorrhoidal Artery Ligation by Morinaga et al. [22] and Recto-Anal Repair by Dal Monte et al. [27], many papers have been published to evaluate and compare this procedure to surgical haemorrhoidectomy [24, 47-49], stapled haemorrhoidopexy [50] and rubber band ligation [51]. Until today none of the above are considered superior although the surgical haemorrhoidectomy was considered the golden standard and the results of the HALRAR procedure are based on short/medium term follow-up only.

In literature, the advantages of the HALRAR procedure are absence of anal wounds with decreased postoperative pain compared to conventional haemorrhoidectomy and stapled haemorrhoidopexy [24, 47-50], but not compared to rubber band ligation [51]. There is a faster return to work/daily activities, and the possibility to organize it as a day case procedure. The anal anatomy and physiology is preserved, resulting in near absent risk of fecal incontinence. There are no reports of serious complications and the procedure can be considered safe. Finally it can be performed under general, spinal or even local anesthesia, which makes it appealing when general anesthesia is contra-indicated.

However, reported disadvantages are recurrent prolapse after HAL, compared to surgical haemorrhoidectomy [24,47-49] and stapled haemorrhoidopexy [50]. The recurrence ameliorated after the introduction of RAR but remains high. Additionally, Lehur et al. [52] published an economic evaluation regarding cost-effectiveness, comparing HALRAR and stapled haemorrhoidopexy. HALRAR is more expensive compared to surgical haemorrhoidectomy and stapled haemorrhoidopexy, which is only partially compensated by the shorter 'sick leave' of patients. Their conclusion states that HALRAR can be cost-effective when performed in under 35 minutes, with outpatients. This statement makes our mean operating time, 44.5 minutes, almost 10 minutes too long.

This study was performed to address the need for long term results after HAL and HALRAR and presents outcomes after 10-year follow-up. The decision to perform the HALRAR procedure was mainly based on the patients' symptoms and clinical findings because symptomatology is often poorly correlated to the grade of haemorrhoidal disease [5], and literature states that haemorrhoidal artery ligation can be successfully performed in all stages of haemorrhoidal disease [30]. Most of the patients had haemorrhoidal disease grade II, but patients with grade I – IV haemorrhoidal disease were treated.

During the 10-year period, the applied sutures and mucopexies were well kept in the operative report, as is visualized in the pie chart (Figure 2 & 3). The odd-numbered clock positions are highlighted and account for 60.17% of all sutures. The remaining 39.83% are applied in even-numbered clock positions with the highest frequency at 2 and 4 o'clock. Although determining the position of the sutures is subjective, over 1/3rd of the terminal branches would be missed if it were not for the Doppler-assistance, conform the literature [31]. So we consider the Doppler-assistance as a necessary tool to correctly localize all the terminal branches of the superior rectal artery. On the other hand, we had some trouble to silence the Doppler signal after ligation, which has been reported in literature as well. This could be explained by the statements of Aigner et al. [53] and Schuurman et al. [36], that the Doppler equipment operate at 7-8 MHz, where they can detect deeper rather than superficial arteries that may not directly contribute to the blood supply of the haemorrhoidal piles. These deeper arteries cannot be ligated by suture. Future clinical research in this field should investigate the role of the Doppler-assistance in Haemorrhoidal Artery Ligation.

As for the Recto-Anal Repair, the pie chart also shows a total of 68.33% sutures placed in the odd-numbered positions and the remaining 31.67% in the even-numbered positions. These results are comparable to the distribution of the HAL sutures. This seems logical as the haemorrhoidal piles grow where there is excessive blood flow in a terminal branch of the superior rectal artery.

Postoperative data showed that 74.82% of the procedures could be performed in day clinic. Which is important to attribute to the cost-

effectiveness of the procedure as mentioned above [52].

Postoperative pain was evaluated by the Visual Analog Scale (VAS) pain score and resulted in a wide range of pain perception among patients. Statistical analysis reveals that the level of postoperative pain significantly increased when RAR was added to the HAL procedure (Figure 5). Still a mean VAS score of 5 is rather high as other papers report mean VAS scores of 2.1-3.1 post-procedure [54, 55]. Although, comparing our results to those of Schuurman JP et al. [56], a VAS score between 5-6 is normal on the first postoperative day. The Visual Analog Scale was one of the subjects in the questionnaire, which, for some patients, must be difficult to report correctly ten years after surgery, without a medically trained supervisor present. Another explanation could be that the RAR procedure is continued beneath the dentate line, where pain receptors are present.

Regarding postoperative complications, a striking 33.9% of patients reported they experienced some postoperative complication(s). Most reported are anal pain, anal blood loss and haemorrhoidal thrombosis. Because this number is exceptionally high and the answers from the questionnaire did not match the postoperative information reported in the patient record, this was further investigated. When the results are based solely on the patient record, there were postoperative complications in 11.3% (in literature 6-17% [22-24, 51]). Anal pain remains the most abundant, followed by haemorrhoidal thrombosis and urinary retention (Figure 6) .

We believe that the liberal documentation of postoperative complications by the patients are biased because of a response rate of 56.6%, a non-validated questionnaire and the lack of medical supervision while filling out the questionnaire. Furthermore, some patients were treated more than five years ago, which could make it difficult to correctly remember the postoperative phase. The results from patients records alone are more comparable to previously reported postoperative complications. We presume that, to report a correct postoperative complication rate, a randomized study with long-term follow-up is necessary where postoperative complications are reported by a member of the medical staff.

The majority of patients (85.8%) were seen one month after surgery. In the questionnaire they were asked to formulate their residual complaints after one month. The results are shown in Figure 8. Statistical analysis showed a significant reduction in symptomatology for every symptom, except for fecal incontinence, which had the same prevalence pre- and postoperatively.

As for the recurrence rate, 44.4% of patients reported the need for additional treatment regarding haemorrhoidal disease. 33.3% still needed conservative or medical measures to minimize symptoms. 12.4% got an additional minimally invasive (non-surgical) procedure, i.e. photocoagulation, rubber band ligation, sclerotherapy. In 14.4% redo HAL or HALRAR surgery was performed and in 9.2% a surgical haemorrhoidectomy was necessary. These results are confirming the previously reported concerns about recurrence of the disease, which seems to gradually increase in time [12, 31, 35]. As reported earlier, there was no significant difference in the need for additional treatment after HAL or HALRAR.

When we looked at the satisfaction after surgery, 84.4% of patients were satisfied (very satisfied, satisfied and neutral) after surgery and 73.8% would consider the same surgery if needed. The safisfaction rate is comparable to other studies (82-92%) [9,25,31,32,55]. Only 8.8% would not consider the HALRAR procedure again. Wilkerson et al. [25] reports a similar 10%.

This study had several limitations. It is a single centre, single surgeon, open, non - randomized study, consisting of a non validated questionnaire, filled out by patients without medical support and no clinical re-evaluation. This leads to considerable bias and confounding factors. It was performed to analyze the first ten years of performing HALRAR in our centre, to evaluate the results and compare them to other published papers regarding this subject and search for ways to improve.

Conclusion

This paper is the first to report long-term results after HALRAR procedures. Our study shows a significant decrease in symptomatology and good patient satisfaction, however it also confirms recently published concerns about high recurrence rates and need for re-interventions. Prospective randomized trials are needed to evaluate long term results compared to other surgical techniques.

References

1. Scheyer M, Antonietti E, Rollinger G et al. Doppler-guided hemorrhoidal artery ligation. ***American Journal of Surgery 2006***;**191(1)**:89-93.
2. Loder PB, Kamm MA, Nicholls RJ, Phillips RK. Haemorrhoids: pathology, pathophysiology and aetiology. ***British Journal of Surgery*** 1994;**81(7)** :946-54.
3. Bruch HP, Roblick UJ. Pathophysiologie des Hämorrhoidalleidens. ***Der Chirurg*** 2001;**72(6)**:656-9.
4. Sneider EB, Maykel JA. Diagnosis and management of symptomatic hemorrhoids. ***Surgical Clinics of North America*** 2010;**90(1)**:17-32.
5. Gerjy R, Lindhoff-Larson A, Nyström PO. Grade of prolapse and symptoms of haemorrhoids are poorly correlated: result of a classification algorithm in 270 patients. ***Colorectal Disease*** 2008;**10(7)**:694-700.
6. Goligher JC. Haemorrhoids or piles. In: **Surgery of the Anus Rectum and Colon,** 4th edn. London: Baillere Tindall, 1980; 93–135.
7. Janssen JWM. Consensus hemorroïden [in Dutch]. ***Nederlands Tijdschrift Geneeskunde*** 1994;**138**:2106-9.
8. MacRae HM, McLeod RS. Comparison of hemorrhoidal treatment modalities. ***Diseases of the Colon & Rectum*** 1995;**38(7)**:687-94.
9. De Vries BW, Van Der Beek ES, De Wijkerslooth LR et al. Treatment of grade 2 and 3 hemorrhoids with Doppler-guided hemorrhoidal artery ligation. ***Digestive Surgery*** 2007;**24(6)**:436-40.
10. Johanson JF, Rimm A. Optimal nonsurgical treatment of hemorrhoids: a comparative analysis of infrared coagulation, rubber band ligation and injection sclerotherapy. ***American Journal of Gastroenterology*** 1992;**87**:1600-6.
11. Hardy A, Chan CL, Cohen CR. The surgical Management of Haemorrhoids– A Review. ***Digestive Surgery*** 2005;**22**:26-33.
12. Giamundo P. Advantages and limits of hemorrhoidal dearterialization in the treatment of symptomatic hemorrhoids. ***World Journal of Gastrointestinal Surgery*** 2016;**8(1)**:1.
13. Shanmugam V, Thaha MA, Rabindranath KS et al. Systematic review of randomized trials comparing rubber band ligation with excisional haemorrhoidectomy. ***British Journal of Surgery*** 2005;**92(12)**:1481-7.
14. Milligan ET, Morgan CN, Jones L, Officer R. Surgical anatomy of the anal canal, and the operative treatment of haemorrhoids. ***The Lancet*** 1937;**230(5959)**:1119-24.
15. Parks AG. The surgical treatment of haemorrhoids. ***British Journal of Surgery*** 1956;**43(180)**:337-51.
16. Ferguson JA, Heaton JR. Closed hemorrhoidectomy. ***Diseases of the Colon & Rectum*** 1959;**2(2)**:176-9.
17. Greenberg R, Karin E, Avital S, et al. First 100 cases with Doppler-guided hemorrhoidal artery ligation. ***Diseases of the Colon & Rectum*** 2006;**49(4)**:485-9.
18. Ho YH, Cheong WK, Tsang C, et al. Stapled hemorrhoidectomy—cost and effectiveness. Randomized, controlled trial including incontinence scoring, anorectal manometry, and endoanal ultrasound assessments at up to three months. ***Diseases of the Colon & Rectum*** 2000;**43(12)**:1666-75.
19. Longo A. Treatment of hemorrhoids disease by reduction of mucosa and hemorrhoidal prolapse with a circular stapler suturing device: A new procedure. In: P***roceedings of the 6th World Congress of Endoscopic Surgery***, Rome, Italy,1998.

20. Pernice LM, Bartalucci B, Bencini L, et al. Early and late (ten years) experience with circular stapler hemorrhoidectomy. ***Diseases of the Colon & Rectum*** 2001;**44(6)**:836-41.
21. halaby R, Desoky A. Randomized clinical trial of stapled versus Milligan—Morgan haemorrhoidectomy. ***British Journal of Surgery*** 200;**88(8)**:1049-53.
22. Morinaga K, Hasuda K, Ikeda T. A novel therapy for internal hemorrhoids: ligation of the hemorrhoidal artery with a newly devised instrument (Moricorn) in conjunction with a Doppler flowmeter. A***merican Journal of Gastroenterology*** 1995;**90(4)**:610-3.
23. Sohn N, Aronoff JS, Cohen FS, Weinstein MA. Transanal hemorrhoidal dearterialization is an alternative to operative hemorrhoidectomy. ***American Journal of Surgery*** 2001;**182(5)**:515-9.
24. Bursics A, Morvay K, Kupcsulik P, Flautner L. Comparison of early and 1-year follow-up results of conventional hemorrhoidectomy and hemorrhoid artery ligation: a randomized study. ***International Journal of Colorectal Disease*** 2004;**19(2)**:176-80.
25. Wilkerson PM, Strbac M, Reece-Smith H, Middleton SB. Doppler-guided haemorrhoidal artery ligation: long-term outcome and patient satisfaction. ***Colorectal Disease*** 2009;**11(4)**:394-400.
26. Bronstein M, Issa N, Gutman M, Neufeld D. Ligation under vision of haemorrhoidal cushions for therapy of bleeding haemorrhoids. ***Techniques in Coloproctology*** 2008;**12(2)**:119-22.
27. Dal Monte PP, Tagariello C, Giordano P, et al. Transanal haemorrhoidal dearterialisation: nonexcisional surgery for the treatment of haemorrhoidal disease. ***Techniques in Coloproctology*** 2007;**11(4)** :333-9.
28. Felice G, Privitera A, Ellul E, Klaumann M. Doppler-guided hemorrhoidal artery ligation: an alternative to hemorrhoidectomy. ***Diseases of the Colon & Rectum*** 2005;**48(11)**:2090-3.
29. National Institute for Health and Clinical Excellence. Interventional procedure guidance 342 haemorrhoidal artery ligation. 2010. Available from https://www.nice.org.uk/guidance/ipg342/resources/haemorrhoidal-artery-ligation-1899867569868997
30. Pucher PH, Sodergren MH, Lord AC, et al. Clinical outcome following Doppler-guided haemorrhoidal artery ligation: a systematic review. ***Colorectal Disease*** 2013;**15(6)**:e284-94..
31. Avital S, Inbar R, Karin E, Greenberg R. Five-year follow-up of Doppler-guided hemorrhoidal artery ligation. ***Techniques in Coloproctology*** 2012;**16(1)**:61-5.
32. Wałęga P, Scheyer M, Kenig J, et al. Two-center experience in the treatment of hemorrhoidal disease using Doppler-guided hemorrhoidal artery ligation: functional results after 1-year follow-up. ***Surgical Endoscopy*** 2008;**22(11)**:2379.
33. 33. Giordano P, Overton J, Madeddu F, et al. Transanal hemorrhoidal dearterialization: a systematic review. ***Diseases of the Colon & Rectum*** 2009;**52(9)**:1665-71.
34. Figueiredo MN, Campos FG. Doppler-guided hemorrhoidal dearterialization/transanal hemorrhoidal dearterialization: Technical evolution and outcomes after 20 years. ***World Journal of Gastrointestinal Surgery*** 2016;**8(3)**:232-7.
35. Faucheron JL, Gangner Y. Doppler-guided hemorrhoidal artery ligation for the treatment of symptomatic hemorrhoids: early and three-year follow-up results in 100 consecutive patients. ***Diseases of the Colon & Rectum*** 2008;**51(6)**:945-9.
36. Schuurman JP, Go PM, Bleys RL. Anatomical branches of the superior rectal artery in the distal rectum. ***Colorectal Disease*** 2009;**11(9)**:967-71.
37. Avital S, Inbar R, Karin E, Greenberg R. Is Doppler ultrasonography essential for hemorrhoidal artery ligation? ***Techniques in Coloproctology*** 2012;**16(4)**:291-4.
38. Szmulowicz UM, Gurland B, Garofalo T, Zutshi M. Doppler-guided hemorrhoidal artery ligation: the experience of a single institution. ***Journal of Gastrointestinal Surgery*** 2011;***15(5)***:803-8.
39. Pol RA, Van Der Zwet WC, Hoornenborg D, et al. Results of 244 consecutive patients with hemorrhoids treated with Doppler-guided hemorrhoidal artery ligation. ***Digestive Surgery*** 2010;**27(4)**:279-84.
40. Forrest NP, Mullerat J, Evans C, Middleton SB. Doppler-guided haemorrhoidal artery ligation with recto anal repair: a new technique for the treatment of symptomatic haemorrhoids. ***International Journal of Colorectal Disease*** 2010;**25(10)**:1251-6.
41. Scheyer M. Doppler-guided recto-anal repair: a new minimally invasive treatment of hemorrhoidal disease of all grades according to Scheyer and Arnold. G***astroentérologie Clinique et Biologique*** 2008;**32(6)**:664.
42. Satzinger UL, Feil WO, Glaser KA. Recto anal repair (RAR): a viable new treatment option for high-grade hemorrhoids. One year results of a prospective study. ***Pelviperineology*** 2009;**28(2)**:37-42.
43. Zagryadskiy E, Gorelov SI. Transanal doppler-guided hemorrhoidal artery ligation and recto anal repair vs closed hemorrhoidectomy for treatment of grade III-IV hemorrhoids. a randomized trial. ***Pelviperineology*** 2011;**30**:107-12.
44. Walega P, Krokowicz P, Romaniszyn M, et al. Doppler guided haemorrhoidal arterial ligation with recto-anal-repair (RAR) for the treatment of advanced haemorrhoidal disease. ***Colorectal Disease*** 2010 Oct 1;12(10Online).
45. Conaghan P, Farouk R. Doppler-guided hemorrhoid artery ligation reduces the need for conventional hemorrhoid surgery in patients who fail rubber band ligation treatment. ***Diseases of the Colon & Rectum*** 2009;**52(1)**:127-30.
46. Theodoropoulos GE, Sevrisarianos N, Papaconstantinou J, et al. Doppler-guided haemorrhoidal artery ligation, rectoanal repair, sutured haemorrhoidopexy and minimal mucocutaneous excision for grades III–IV haemorrhoids: a multicenter prospective study of safety and efficacy. ***Colorectal Disease*** 2010;**12(2)**:125-34.
47. Elmér SE, Nygren JO, Lenander CE. A randomized trial of transanal hemorrhoidal dearterialization with anopexy compared with open hemorrhoidectomy in the treatment of hemorrhoids. D***iseases of the Colon & Rectum*** 2013;**56(4)**:484-90.
48. De Nardi P, Capretti G, Corsaro A, Staudacher C. A prospective, randomized trial comparing the short-and long-term results of doppler-guided transanal hemorrhoid dearterialization with mucopexy versus excision hemorrhoidectomy for grade III hemorrhoids. ***Diseases of the Colon & Rectum*** 2014;**57(3)**:348-53.
49. Denoya P, Tam J, Bergamaschi R. Hemorrhoidal dearterialization with mucopexy versus hemorrhoidectomy: 3-year follow-up assessment of a randomized controlled trial. ***Techniques in Coloproctology*** 2014;**18(11)**:1081-5.
50. Sajid MS, Parampalli U, Whitehouse P, et al. A systematic review comparing transanal haemorrhoidal de-arterialisation to stapled haemorrhoidopexy in the management of haemorrhoidal disease. ***Techniques in Coloproctology*** 2012;**16(1)**:1-8.
51. Brown SR, Tiernan JP, Watson AJ, et al. HubBLe Study team. Haemorrhoidal artery ligation versus rubber band ligation for the management of symptomatic second-degree and third-degree haemorrhoids (HubBLe): a multicentre, open-label, randomised controlled trial. ***Lancet*** 2016;**388(10042)**:356-64.
52. Lehur PA, Didnée AS, Faucheron JL, et al. Cost-effectiveness of new surgical treatments for hemorrhoidal disease: a multicentre randomized controlled trial comparing transanal Doppler-guided hemorrhoidal artery ligation with mucopexy and circular stapled hemorrhoidopexy. ***Annals of Surgery*** 2016;**264(5)**:710-6.
53. Aigner F, Bodner G, Conrad F, et al. The superior rectal artery and its branching pattern with regard to its clinical influence on ligation techniques for internal hemorrhoids. ***The American Journal of Surgery*** 2004;**187(1)**:102-8.
54. Festen S, Van Hoogstraten MJ, Van Geloven AA, Gerhards MF. Treatment of grade III and IV haemorrhoidal disease with PPH or THD. A randomized trial on postoperative complications and short-term results. ***International Journal of Colorectal Disease*** 2009;**24(12)**:1401-5.
55. Avital S, Itah R, Skornick Y, Greenberg R. Outcome of stapled hemorrhoidopexy versus doppler-guided hemorrhoidal artery ligation for grade III hemorrhoids. ***Techniques in Coloproctology*** 2011;**15(3)**:267-71.
56. Schuurman JP, Rinkes IH, Go PM. Hemorrhoidal artery ligation procedure with or without Doppler transducer in grade II and III hemorrhoidal disease: a blinded randomized clinical trial. ***Annals of Surgery*** 2012;**255(5)**:840-5.

Impact of Surgeon Volume and Sub-Speciality on Cholecystectomy Outcomes: A Ten Year Experience

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Abstract

Introduction: Cholecystectomy guidelines in the UK recommend surgeons perform more than 40 procedures per year. This retrospective study aims to assess variation in outcomes in patients operated by high and low volume surgeons as well as those that work in an upper GI specialist unit.

Methods: Elective cholecystectomies performed between 2003 and 2012 were included. The data was analysed by volume with surgeons performing over 40 per year or fewer, and by specialism with surgeons in the upper GI directorate compared to others. Results were analysed by the Fishers Exact test and Odds Ratios for categorical variables and independent t-test for continuous variables.

Results: During the study period, 5350 patients underwent cholecystectomy. In the low volume group the rate of conversion to an open procedure was significantly higher 4.4 vs. 1.2% OR 3.82 (2.61-5.59), the day case rate was lower 25.2% vs. 46.3% OR 2.56 (2.27-2.89), and the length of stay was longer 1.45 days vs. 1.02 days ($p<0.0001$). These findings were similarly demonstrated in the non upper GI specialist group; conversion to open 3.8% vs. 0.6% OR 6.57 (3.76-11.48), day case rate 31.4% vs. 47.2% 1.95(1.75-2.18), length of stay 1.32 days vs. 1.01 days ($P<0.0001$). In addition, a higher reoperation within 30 days rate 4.8% vs. 2.6%, 1.91 (1.41-2.59) was reported when compared to upper GI specialists.

Conclusions: This data supports the national guidelines for surgeon volume and cholecystectomy, and demonstrates an improvement in outcomes in patients operated by surgeons working within a specialist unit.

Key Words: Morbidity, Mortality, Cholecystectomy.

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Introduction

Gallstone disease is prevalent in approximately 15% of the adult population in the UK. (1) Management for symptomatic gallstone disease in the minimally invasive era is laparoscopic cholecystectomy (LC) with over 60,000 performed in 2014-15 in England (2) LC has historically been considered a common 'general surgical' operation. However, since its advent in the early 1990's there has been wide variation in reported outcomes across the spectrum of key performance indicators.

Evidence drawn from other fields demonstrates that surgical volume is associated with improved outcomes (3). Hobbs et al. 2006 reviewed over 30000 LC undertaken in Australia between 1988 and 1998 demonstrating higher risk for all complications and bile duct injuries in patients whose surgeon had completed less than 200 LC in the preceding 5 years (4).

The following table (Table 1) reports the data from six studies that have assessed surgeon volume and outcomes after LC.

Further to Table 1, Harrison et al. reviewed 59918 LC in Scotland grouped by hospital volume rather than individual surgeon, which showed that a moderate volume hospital had the highest complication rates and 30 day mortality rates, when compared to both high and low volume groups. Length of stay was significantly shorter in the high volume hospital (10).

The NHS Institute for Innovation and Improvement has extrapolated Hobbs study to recommend minimal surgical volume of 40 LC per year per surgeon as a benchmark for improving the quality of patient care (11).

There is however a paucity of contemporary robust direct evidence in UK practice and therefore recommendations have been largely ignored nationally due to the logistic difficulty of implementation allied to surgical 'ego'. The aims of this study were to:

1. Assess outcomes of cholecystectomy when performed by high vs. low volume or specialist vs. non-specialist surgeons;
2. Assess whether adherence to NICE guidelines will improve outcomes.

Materials and Methods

Data were collected from the Hospitals Statistics database for a ten year period between 01/01/2003 - 31/12/2012. The trust serves a heterogeneous population in the West Midlands and the Department of Surgery comprises of specialist Colorectal, Upper GI and Breast surgeons, as well as general surgeons.

6193 cholecystectomies were identified coded as J181, J182, J183, J184, J185, J188, J189. Emergency admissions resulting in cholecystectomy were excluded, leaving 5432 elective cholecystectomies. Of these, cholecystectomies were excluded if the named consultant had performed fewer than 5 cholecystectomies within the 10 year period or worked for the trust for less than 60 days. This was to exclude cholecystectomies performed by incorrectly coded consultants and short term locums. This resulted in 5350 cholecystectomies for analysis.

Consultant surgeon data was analysed for total number of urgent and elective cholecystectomies within the study period. This was combined with the number of days between the first and last cholecystectomy performed by that surgeon in the study period to give a cholecystectomy/day ratio. This was extrapolated to give a cholecystectomy per annum ratio (Figure 1).

Table 1 Cholecystectomy and Surgeon volume.

Author and year of publication	Year data collected	Surgery	N	High Volume/ Low volume group	Outcomes	Difference
Hobbs et al 2006 (4)	1980-1999	LC and OC	33309	Stratified 1-50 51-100 101-200 201-300 >300 (over 5 years)	All complications	OR 1.72(1.21-2.46) 1.52(1.03-2.25) 1.35(0.97-1.89) 1.10 (0.78-1.55) Reference group
Boddy et al 2006 (5)	1996-2005	LC and OC	4139	Upper GI surgeons vs. Other	Conversion rate Length of stay	3.4 vs. 14.1% (p<0.001) 2.0 vs. 3.6% (p<0.001)
Csikesz et al 2009 (6)	1999-2005	Urgent LC and OC	80149	>15 per year 1-15 per year	Conversion rate Prolonged length of stay Bile duct injury	8.0 vs. 11.8% (p<0.0001) 12.8 vs. 11.1% (p<0.0001) 0.15 vs. 0.22 (p=0.03)
Lee et al (7)	1998 – 2002	Elective LC	916	By each surgeon 502 192 147 75 (over 4.3 years)	All complications (adjusted)	OR (95% CI) Reference Group 7.3 (1.47 36.7) NS 5.43 (0.77-38.48)
Murphy et al (8)	1998 – 2006	Elective and Urgent LC	1102071	<12 per year 12-35 per year >35 per year	Major post op complication	Low 7.0% Medium 6.8% High 6.7% (p<0.0001)
Donkervoort et al (9)	2004-2008	Elective and urgent LC	942	<10 11-20 >30	Mortality Major post op complication	No significant difference between groups

The data were examined in two different analyses. The first analysis was to compare cholecystectomy outcomes when grouped by surgeons that performed ≥ 40/annum and <40/annum. The second analysis was to compare outcomes when grouped by upper GI surgeons or others. Upper GI surgeons were defined as being employed in the upper GI directorate, which in this trust provides a gallbladder, bariatric and oesophagogastric benign and cancer service.

Data was interrogated for demographics, conversion rate, complication rate, day case rate, length of stay, reoperation rate, readmission within 30 day rate and significant bile duct injury (BDI) rate. Significant BDI was defined as bile duct injury requiring surgical reconstruction. Results were analysed by the Fishers Exact test and Odds Ratios with 95% Confidence Intervals for categorical variables and the independent t-test for continuous variables. Data was analysed with SPSS software version 22.0 (IBM Corp 2013, Armonk, NY).

No consent or IRB approval was needed for this study.

Results

5350 cholecystectomies were included, the mean age was 49 years and 79.3% were female. The data was examined in two separate analyses as outlined in the methods and tabulated below (Tables 2, 3 and 4).

Conversion to open and open cholecystectomy rates

In this centre the intention for elective LC was 99.0%, with only 1% of cases planned as open procedures. Both the high and low volume groups had an equivalent rate of planned laparoscopic and open cholecystectomy. However in the low volume group there was a significantly higher odds of conversion from laparoscopic to open cholecystectomy OR 3.82 (2.61-5.59). There was an even higher odds ratio in the non specialist unit OR 6.57 (3.76-11.48) when compared to the upper GI unit.

Day case rates

The overall day case rate was 38.3% for cholecystectomy. The day case rate was significantly higher in the high volume group OR 2.56 (2.27-2.89) and upper GI unit OR 1.95 (1.75-2.18).

Reoperation rates

The overall 30 day reoperation rate was 3.9% rising to 5.8% at 90 days. The 30 and 90 day reoperation rates were equivalent in the high and low volume groups. The 30 day reoperation rate was significantly higher in the non specialist unit OR 1.91 (1.41-2.59), but by 90 days the reoperation rate was equivalent.

Readmission rates

The overall emergency readmission within 30 days was 5.0%. This was not significant in either analysis.

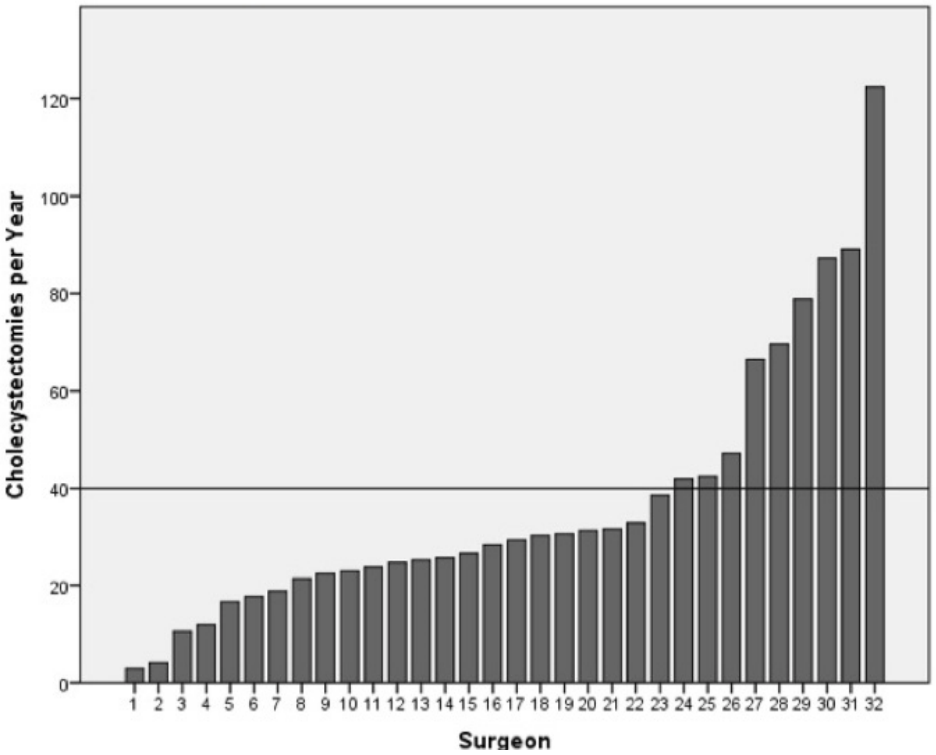

Figure 1. Graph to show surgeon volume per year.

Table 2 Population characteristics by group.

	≥ 40 per annum	<40 per annum		Upper GI Directorate	Non Upper GI Directorate	
N	n = 3325	n = 2025		n = 2351	n = 2999	
Mean Age	49.12	49.88	p=0.079	50.40	48.15	p<0.0001
Female	2660 (79.3%)	1585 (78.3%)	p=0.134	1894 (80.6%)	2351 (78.4%)	p=0.053

Fishers Exact Test

Table 3 Comparison between high and low volume groups.

	≥ 40 per annum n = 3325	<40 per annum n = 2025	P value	OR (95% CI)
Intention LC	3290 *(98.9%)*	2007 *(99.1%)*	p=0.670	0.843 (0.48-1.50)
Conversion to open	39 *(1.2%)*	88 *(4.4%)*	p<0.0001	3.82 (2.61-5.59)*
Day case	1540 *(46.3%)*	510 *(25.2%)*	p<0.0001	2.56 (2.27-2.89)*
Reoperation within 30 days	129 *(3.9%)*	77 *(3.8%)*	p=0.942	0.979 (0.77-1.36)
Reoperation within 90 days	192 *(5.8%)*	119 *(5.9%)*	p=0.904	1.02 (0.81-1.29)
Readmission within 30 days	154 *(4.6%)*	115 *(5.7%)*	p=0.094	0.807 (0.629-1.034)
In-hospital Mortality	1 *(0.03%)*	1 *(0.05%)*	p=1	0.61 (0.04-9.74)
CBD injury rate	2 *(0.06%)*	2 *(0.10%)*	p=0.636	0.609 (0.09-4.33)
Mean Length of Stay (days)	*1.02*	*1.45*	p<0.0001*	

Fishers Exact Test and Odds Ratios are given for categorical variables, *indicates significance
Mean independent t-test are given for non-categorical variables *indicates significance

Table 4 Comparison between Upper GI and Non Upper GI directorate.

	≥ 40 per annum n = 3325	<40 per annum n = 2025	P value	OR (95% CI)
Intention LC	2333 *(99.2%)*	2964 *(98.8%)*	p=0.165	1.53 (0.87-2.71)
Conversion to open	14 *(0.6%)*	113 *(3.8%)*	p<0.0001*	6.57 (3.76-11.48)
Day case	1109 *(47.2%)*	941 *(31.4%)*	p<0.0001*	1.95 (1.75-2.18)
Reoperation within 30 days	61 *(2.6%)*	145 *(4.8%)*	p<0.0001*	1.91 (1.41-2.59)
Reoperation within 90 days	129 *(5.5%)*	182 *(6%)*	p=0.378	1.11 (0.88-1.40)
Readmission within 30 days	103 *(4.4%)*	166 *(5.5%)*	p=0.059	0.78 (0.61-1.01)
In-hospital Mortality	1 *0.04%*	1 *0.03%*	p=1	(0.08-20.4)
CBD injury rate	2 *(0.09%)*	2 *(0.06%)*	p=1	1.28 (0.18-9.06)
Mean Length of Stay (days)	1.01	1.32	p<0.0001*	

N(%) and Fishers Exact Test are given for categorical variables, *indicates significance
Mean independent t-test are given for non-categorical variables *indicates significance

Bile Duct Injury
The overall significant bile duct injury rate was 0.07% and this was not significantly different in any group.

In-hospital Mortality
Overall In-hospital mortality was 0.04%, with 1 patient in each group.

Length of Stay
Length of Stay was significantly shorter in both the upper GI unit and in surgeons with a volume of more than 40 cases per annum, 1.01 vs. 1.32 days (p<0.0001) and 1.02 vs. 1.45 days (p<0.0001) respectively.

Discussion

An increasing volume of evidence supports the concept of high surgical volume (unit and individual) being directly correlated with improved patient outcomes. The volume effect has been demonstrated most convincingly in major surgery (3) but this has not been universally accepted or fully implemented within the NHS.

The recommendations for cholecystectomy have previously been extrapolated from an historic Australian study (4) and largely corroborated by heterogeneous retrospective papers (5,6,8). Critical review would question the use of sub group analysis of a continuous variable that has been levelled at other volume studies. However, results appear to translate to improved length of stay, complication and conversion rates but additionally highlight a high degree of random cause variation, which is particularly demonstrated in the variation in the major complication of bile duct injury (10).

This study reports on a large single centre cholecystectomy series that reflects NHS practice. This data confirms that LC is a safe procedure with an associated mortality of 0.4 per 1,000 and a major bile duct injury rate of 0.7 in 1,000. However this data does describe variability in outcomes related to surgeon volume and specialty. There is a 3-fold higher risk of conversion to open procedure in surgeons that perform less than 40 LC per year, and 6 fold increase in risk of requiring conversion in surgeons that do not work in a specialist upper GI unit. Open cholecystectomy is associated with longer in patient stays and morbidity including pneumonia and wound infection (12).

There is also a doubling of patients that stay one night or more if the cholecystectomy is performed by a low volume or non-specialist surgeon. Performing LC as day surgery has become the 'gold standard' of care. Again the evidence base to support this on clinical outcome is limited (13) and subject to relatively small sample sizes that are potentially amenable to random error and risk of bias. There is however a number of major drivers relating to reduced bed occupancy and significant cost savings, estimated to be £6.1 million for the NHS if fully delivered reflected in 'Best Practice Tariff'. Despite this, there is an 8-fold variation in day-case LC rates across hospitals in England largely attributable to common cause variation (11).

The difference in surgeon volume and experience has been reported in other fields (14,15) and variably in cholecystectomy, however this study adds to the data of five previous studies (4-8) that surgeon volume and specialism does positively improve outcome. Although this may be influenced by special case variation in low volume surgeons, a sample group sub analysis looking at case selection suggests this bias would exacerbate positive differences seen. Future work to control for this would require prospective data collection to enable an analysis for features such as previous episodes of cholecystitis, pancreatitis, pain profile prior to cholecystectomy and medical co-morbidities as well as history of previous ERCP.

Conclusion

NICE guidelines recommend that LC should be performed by surgeons performing more than 40 procedures per year. This data

supports that recommendation, with better outcomes in patients treated by high volume and/or specialist surgeons. These findings should be considered when redesigning gallbladder services. It is therefore reasonable to suggest that surgery should be performed by surgeons attaining a set surgical volume, allied to assurances of training and outcome monitoring.

References

1. Gallstone disease: Diagnosis and Management. The National Institute for Health and Care Excellence (NICE) 2014; Available at: https://www.nice.org.uk/guidance/cg188. Accessed 23/06/2018
2. Gallstone Commissioning Guidelines - 2016. Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland. Available at: http://www.augis.org/augis-guidelines. Accessed 23/06/2018
3. Maruthappu M, Gilbert BJ, El-Harasis MA, et al. The influence of volume and experience on individual surgical performance: a systematic review. A***nnals of Surgery*** 2015;**261(4)**:642-7.
4. Hobbs MS, Mai Q, Knuiman MW, Fletcher DR, Ridout SC. Surgeon experience and trends in intraoperative complications in laparoscopic cholecystectomy. ***British Journal of Surgery*** 2006;**93(7)**:844-53.
5. Boddy AP, Bennett JM, Ranka S, Rhodes M. Who should perform laparoscopic cholecystectomy? A 10-year audit. Surgical ***Endoscopy*** 2007;**21(9)**:1492-7.
6. Csikesz NG, Singla A, Murphy MM, Tseng JF, Shah SA. Surgeon volume metrics in laparoscopic cholecystectomy. ***Digestive Diseases and Sciences*** 2010;**55(8)**:2398-405.
7. Lee KT, Chang WT, Huang MC, Chiu HC. Influence of surgeon volume on clinical and economic outcomes of laparoscopic cholecystectomy. ***Digestive Surgery*** 2004;**21(5-6)**:406-12.
8. 8. Murphy MM, Ng SC, Simons JP, et al. Predictors of major complications after laparoscopic cholecystectomy: surgeon, hospital, or patient? ***Journal of the American College of Surgeons*** 2010;**211(1)**:73-80.
9. 9. Donkervoort SC, Dijksman LM, Versluis PG, Clous EA, Vahl AC. Surgeon's volume is not associated with complication outcome after laparoscopic cholecystectomy. ***Digestive Diseases and Science*** 2014;**59(1)**:39-45.
10. 10. Harrison EM, O'Neill S, Meurs TS, et al. Hospital volume and patient outcomes after cholecystectomy in Scotland: retrospective, national population based study. ***British Medical Journal*** 2012;**344**:e3330.
11. 11. NHS Institute for Innovation and Improvement. Focus on: cholecystectomy: delivering quality and value. 2006. Available at: https://www.qualitasconsortium.com/index.cfm/reference-material/delivering-value-quality/focus-on-cholecystectomy/ Accessed 23/06/2018.
12. 12. Coccolini F, Catena F, Pisano M, et al.Open versus laparoscopic cholecystectomy in acute cholecystitis. Systematic review and meta-analysis. ***International Journal of Surgery*** 2015;18:196-204.
13. 13. Gurusamy KS, Junnarkar S, Farouk M, Davidson BR. Day-case versus overnight stay for laparoscopic cholecystectomy. ***Cochrane Database of Systemic Reviews*** 2008;(3):CD006798. doi(3):CD006798.
14. 14. Borowski DW, Kelly SB, Bradburn DM, et al. Northern Region Colorectal Cancer Audit Group. Impact of surgeon volume and specialization on short-term outcomes in colorectal cancer surgery. ***British Journal of Surgery*** 2007;**94(7)**:880-9.
15. 15. Burns EM, Mamidanna R, Currie A, et al.The role of caseload in determining outcome following laparoscopic colorectal cancer resection: an observational study. ***Surgical Endoscopy*** 2014;**28(1)**:134-42.

Economic Advantages of Performing Orthopaedic Surgical Procedures in Ambulatory Surgical Centres Over Hospital Out-Patient Settings

Harjot Uppal

Abstract

A study was conducted to compare the relative efficacy of ambulatory surgery centres (ASCs) and hospital outpatient departments (HOPDs) across eight orthopaedic procedures. The research was motivated by the fact that ASCs are becoming of increasing importance, even vitality, in the performance of a wide array of ambulatory surgical procedures including arthroscopy, arthroplasty, fracture repair, and laminectomy. As HOPDs continue to be hamstrung by resource constraints, ASCs can be seen to be cultivating ever more focused surgical expertise. Moreover, the ASC becomes a steadily more attractive alternative as HOPDs continue to be overburdened by the growing rate of ambulatory surgeries being performed on the hand, foot, ankle, and spine.

HOPD procedures are taxonomized by the ambulatory payment classification (APC) system while ASC procedures are described using current procedural terminology (CPT). A variety of quantitative and qualitative metrics were obtained that demonstrate that ASC procedures receive high marks. Indeed, ASC surgeries typically cost 25 to 50 percent less than their HOPD analogues and sport a 25 percent faster recovery time, partially as a result of dramatically decreased surgical site infections (SSI). Both patients and physicians further expressed a considerable degree of satisfaction with, and even preference for surgical procedures rendered at ASCs. One concern is that since many physicians hold ownership stakes in one or more ASC, this evident qualitative preference may, in fact, reflect personal bias. A follow-up study is postulated that is targeted at both assessing and reducing the effects of this perceived imparity

Keywords: Hospital outpatient department, Orthopaedic procedures, Ambulatory Surgery Centre.

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Introduction

Outpatient surgery has become an integral part of medical care across the globe. For instance, in the United States, the number of major and minor outpatient procedures undertaken in ambulatory surgical centers (ASCs) has risen dramatically over the past four decades. ASCs refer to health care facilities that play a central role in offering patients the much-needed convenience of having surgical procedures performed safely and in a timely manner outside hospital settings. Before the inception of ASCs, virtually all forms of surgeries were conducted in hospitals. Appointments characterized by long waiting periods were common during this time. Patients also spent several in-patient days in recovery. Additionally, medical practitioners faced different challenges, including working from limited operating rooms, difficulty in accessing new surgical equipment, and distractions of prolonged operating turnover times. The problems associated with hospital outpatient departments (HOPDs) compelled practitioners to look for change-driven strategies aimed at improving their performance. Though some countries still perform surgeries in these settings, the U.S. has made tremendous gains with regard to the development of ASCs. Individual physicians in the U.S. have assumed the leading role in promoting ASCs adoption as the cost-effective and a high-quality alternative to inpatient hospital surgical services. Since the inception of ASCs in the U.S., the facilities in question have resulted in high customer care, reduced healthcare costs, high quality, and excellent overall patient and physician satisfaction. ASCs complement managed care practioners, whose primary objective revolves around delivering quality, timely care at a significantly reduced cost. ASCs align perfectly well with the U.S. government's efforts to reduce its healthcare budget. The existing and potential economic benefits directly associated with ASCs involve decreasing costs without compromising patient and physician satisfaction levels.

The recently released current procedural terminology (CPT) codes are outpatient codes that determine the number of billable units of reimbursement that are allowable for a given procedure. HOPDs utilize ambulatory payment classifications (APC) codes for the same purpose. This paper will utilize the available literature on patient clinical outcomes regarding infection and reoperation rates examined over a 90-day period and show that eight common orthopaedic surgical procedures performed in ASCs are more economical compared to them being performed in the hospital outpatient settings. The orthopaedic surgery procedures evaluated are: shoulder arthroscopy with subacromial decompression and distal clavicle resection, knee arthroscopy with anterior cruciate ligament repair, open reduction and internal fixation of bimalleolar ankle fracture, open reduction and internal fixation of distal radius fracture, knee arthroscopy with medial and lateral meniscectomy, total knee arthroplasty, and one level lumbar laminectomy.

Patient Clinical Outcomes

Patients increasingly prefer outpatient surgery performed in ASCs to similar procedures undertaken in hospitals. The trend remains inextricably linked to positive patient clinical outcomes, such as reduced surgical site infections (SSIs) and reoperations, and advantages in cost, quality, and time factors (1). Hospitals continue to face a variety of resource-related challenges, including financial constraints, which inhibit their ability to meet the ever-growing demand for arthroplasty, hand, spine, and foot and ankle surgeries. For example, the Ambulatory Surgery Center Association (ASCA) reported that more than 5,300 ASCs provided over 25 million procedures in the country in 2005 (2). From the economic theory perspective, the rapid growth witnessed in the number of ASCs

serves as a clear indication that the market can expand at an increased rate when there is alignment of incentives of patients, payers, and providers.

SSIs and Reoperation Rates

Reoperation and SSI rates play a pivotal role in determining whether surgical procedures taken in ASCs are cost-effective. In their recent study, Toy et al. (3) set out to investigate the hospital admission and complication rates for patients who have undergone total hip arthroplasty (THA) surgery in an ASC with same-day discharge. Following the recent focus on bundled payments involving a 90-day episode-of-care, the researchers chose the same period to determine possible patient outcomes. Equally important, they reviewed reliable records of patients from two separate ASCs. In addition, they divided the 145 procedures (in 125 patients) involved in two groups based on when they were performed: early or later in surgeon's experience. To achieve the intended results effectively, they recorded any complications, hospital admissions, blood loss, time spent by patients at the facilities, and length of surgery.

This study demonstrates that same-day discharge to the patient's following total hip arthroplasty (THA) can be safely done without increased complications, hospital admissions, reoperations, or emergency room visits. In essence, the researchers established that only one of the 145 procedures, representing 0.7%, required direct admission to the hospital from the ASC (3). At the same time, only three of the arthroplasties (2%) required additional procedures within the global period. It is evident from the study that same-day discharge following THA done in an ASC tends to have limited complications, emergency room transfers, hospital admissions, and reoperations. In addition, with a CPT code of 27447 and APC number of 5115, total knee arthroplasties (TKAs) only costs $9,557.20 in ASCs, compared to $10,122.92 in HOPDs (Table 1) (4) (Near here). As this is a new code for ASCs, this difference in reimbursement is subject to change. Ultimately, the procedure is cheaper and fought with low complication rates when performed in an ASC setting.

In addition to TKAs done in ASCs, medical professionals remain interested in outpatient total elbow arthroplasties (TEAs) and THAs because of the increasing emphasis on efficient and high-quality medical care. In their retrospective study, Stone et al (5) employed a holistic approach to evaluating complications, hospital admissions, and reoperations in 28 patients with outpatient TEA discharged after the procedure for a 90-day period. In the follow-up, they not only recorded and examined postoperative complications but also the range of elbow movement measurements with the sole purpose of assessing the participants' outpatient experience at ASC. After performing univariate and multiple logistic regressions for each of the risk factors, they found that major complications occurred in approximately 7.1% of patients. Additionally, over the 90-day episode-of-care, 39.2% of patients had minor wound problems. Notably, their univariate regression analysis showed that the minor wounds in question had a strong correlation with smoking. Therefore, patient selection for this procedure in an ASC setting is critical.

Apart from reoperation and related complications, surgical site infections (SSIs) remain the most common surgical centre complication and serve as one of the main reasons for unplanned hospital admissions in the immediate aftermath of operations. SSIs account for more than 20 percent of healthcare-associated infections, particularly in hospitalized patients, leading to considerable morbidity, stays prolonged by up to 10 days, increased mortality rates, and cost between $20,000 and $27,600 per admission (6). Referring to the U.S. National Action Plan to Prevent Healthcare-Associated Infections (NAPPHAI), reducing SSIs remains one of the country's priorities. Initially focused on healthcare-associated infections experienced within acute care hospitals and related high-priority areas, the action plan now addresses additional healthcare settings, including ambulatory surgery. As much as there is little information regarding adverse events, such as SSIs, following operations undertaken in the ambulatory settings, the problems directly or indirectly linked to healthcare-associated infections from ASC procedures are minimal6. The researchers arrived at this conclusion based on the evaluation of improved data acquisition using CPT procedure codes for clinically significant site infections (CS-SSIs) associated with ASCs. In fact, at a Surgical Care Affiliate (SCA) surgicenter over a one-year period in Riverside, California, the post-operative infection was less than 1% for over 5,000 procedures7. In essence, the CPT codes enabled them to evaluate and establish the efficiency of performing surgeries in an ASC with the aim of reducing SSIs.

The ability to determine the incidence of CS-SSIs resulting from low-to moderate-risks involved in Medicare-certified outpatient

Table 1 Medicare ASC and HOPD Reimbursement Rates for Eight Orthopaedic Procedures.

Procedure	Medicare ASC Reimbursement	Medicare HOPD Reimbursement
Shoulder Arthroscopy with RCH, SubAcromial Decompression & Distal Acromioclavicular Resection and Debridement	$5,790.82	$10,896.88
Knee ACL Repair	$8,774.80	$16,503.30
Total Hip Arthroplasty	N/A	$10,122.92
Total Knee Arthroplasty	$9,557.20	$10,122.92
Open Reduction / Internal Fixation of Bimalleolar fracture with fluroscopy	$3,027.01	$5,838.73
Open Reduction / Internal Fixation of Distal Radial fracture with fluroscopy	$1,446.45	$5,838.73
Knee Arthroscopy with Medial and Lateral Meniscus Repair	$1,403.42	$2,645.23
Laminectomy with fluroscopy	$3,027.01	$5,838.73

*Total hip arthroplasty is not currently recognized as an outpatient procedure, and total knee arthroplasty has only recently been approved as an out-patient procedure.

surgical settings plays a fundamental role in revealing the effect of ASCs in health care costs. Owens et al. (2014) undertook a retrospective analysis of ASC procedures complicated by various CS-SSIs, which require reoperation. In the study, they employed the use of healthcare cost, state outpatient, and ambulatory surgery databases to examine the information about infectious outcomes in ASCs located in America's geographically dispersed states, including Nebraska, Tennessee, Florida, Georgia, New York, Hawaii, California, and Missouri. These states, which represent about one-third of the country's population, recorded low rates of postsurgical visits because of SSIs. In particular, postoperative acute care visits occurred only in less than three percent of the 1,000 surgical procedures done in ASCs6. The insignificant rate of reoperation often translates to reduced clinical and economic burden given the already concerted effort toward minimizing overall health care cost in the U.S.

Other common ASC procedures that are more likely to produce more SSIs and potentially increase health care costs in the U.S. include anterior cruciate ligament reconstruction (ACL), hernia repair, cholecystectomy, and breast-conserving surgery (BCS). In a recent retrospective cohort study involving persons who had undergone these forms of ambulatory surgical operations, Olsen et al. (8) used commercial insurer claims and cost distribution to determine the impact of SSIs on health costs. Despite the sparse nature of data on SSIs costs following ambulatory surgeries, the researchers adhered to the recommended 90-day postoperative procedure to identify any infections requiring surgery or during the hospitalization period. Using quantile regression to control operative, patient, and postoperative factors, they found few cases involving severe infections, which either resulted in surgical treatment or hospitalization. The cases in question were directly linked to the increased costs of healthcare after the four procedures.

The most important aspect of the study conducted by Olsen revolves around the comparison of results obtained from in-patient surgery facilities and ASCs. In particular, the researchers report that HOPDs were characterized by higher costs for each of the four common procedures than freestanding ASCs, which contributed to lower costs (8). Drawing from patient satisfaction trends in Glenwood Surgery Center (SCA Facility 50138), the researchers attributed the difference in results to the ability of nursing staff in ASCs to address primary concerns, provide the much-needed explanations, and communicate delays in a timely manner [9]. Most importantly, the study has since acknowledged and appreciated the critical role played by medical staff during and after follow-up calls. Ambulatory outpatient surgery facilities serve as the best possible alternative to HOPDs, especially in minor and selective major surgeries involving low risks.

Time/Procedure Length

Time or procedure length remains one of the key aspects of outpatient surgeries. In essence, physicians need to examine four length-of-surgery measures, including 1) time in the operating room, 2) time in surgery (a subset of time in the operating room) 3) time in post-operative care, and 4) total procedure time (time in the operating room, time in postoperative care, and transport time between the operating room and the recovery room) (1). Although previous research has placed much emphasis on documenting differences witnessed in surgery time between HOPDs and ASCs, variations in procedure time tend to reflect only the underlying differences common in-patient characteristics, not those in efficiency between the facilities in question. To resolve this concern effectively, recent research has focused on comparing the relationship between procedure time and total time in the ASC setting, to that in the HOPD setting. In doing so, it becomes clear how health care cost varies based on efficiency between hospital-based surgeries and ambulatory-centered surgical procedures. Estimates obtained from recently sampled and reviewed studies have revealed that time savings for ASCs are shorter than that of HOPDs. In other words, ASCs remain substantially faster at performing low-risk outpatient procedures than hospitals, particularly when observed patient characteristics and procedure type are controlled throughout a study. On average, patients operated in ASCs spent approximately 31.8 fewer minutes than those whose procedures were undertaken in hospitals (1). This represents a 25% difference relative to the operation activities' mean procedure time of about 125 minutes. In this regard, for an HOPD and an ASC that have similar equipment and the same number of recovery rooms and staff, the ASC will be performing more procedures on a daily basis and at a cheaper cost than the hospital outpatient facility. This may explain how more time-efficient ASCs can operate with lower Medicare reimbursed payments per procedure.

The estimated charges for operating a patient in ASCs are between $29 and $80 per minute (1). These charges exclude fees for the anesthesia providers and surgeon involved in the procedure. The researchers' calculation shows that even with the exclusion of time savings as well as physician payments outside a facility's operating room, an ASC could generate higher savings of between $363 and $1,000 per outpatient surgical case. In essence, these findings support the widely held claim that ASCs play a pivotal role in providing outpatient surgery at relatively lower costs than HOPDs.

In addition to their role in reducing procedure time, Medicare-approved ASCs rarely pose significant adverse medical risks to individual patients. Referring to the selection of a covered procedure, particularly those payable under ambulatory surgical center payment system (ASCPPS), each of the stakeholders, including the secretary of Health and Human Services (HHS) involved must focus on selecting safe procedures for patients when performed in an ASC (10). Although, the Secretary of HHS remains tasked with the responsibility of choosing the right procedures, the ultimate decision regarding whether ASCs and HOPDs serve as the most appropriate settings for a surgical procedure is made by responsible physicians based on a patient's individual clinical needs. In the case of patients age 65 and above, the 2010 report released by the Agency for Healthcare Research and Quality (AHRQ) shows that about 32% of this patient population has a high-risk medical history of comorbidities. This is due to increased incidence of chronic illnesses and conditions, such as cancer, arthritis, and lung disease (11). Younger patients presented in operating rooms often have lower-risk medical profiles. With these conflicting clinical needs, a patient is operated either in an ASC or in an HOPD depending on the severity of their comorbidities.

ASCs typically record fewer adverse incidents than procedures performed in physician offices (12). For example, the incident rate of adverse incidents in ambulatory surgical settings and offices occurred 5.3 and 66 per 100,000 surgical procedures, respectively (12). At the same time, the rates witnessed in 100,000 operations were 0.78% and 9.2% in ASCs and physician offices, respectively. Additionally, the relative risks recorded for deaths and injuries for ASCs and offices differed significantly, leading to the conclusion that surgical procedures performed by stand-alone practitioners in their offices have 10-fold increased risks over those performed in an ASC. This fact supports that cost alone should not be the sole driving force for selecting the setting of surgical service. While ASC-based procedures reduce potential hospital admissions, mild to severe injuries, loss of life, and healthcare cost, office-centered surgeries show an increased incidence rate. If each of the office procedures could be done in ASCs, the researchers argue that about six deaths and over 43 procedures could be prevented every year (12).

ASCs remain focused on providing individual patients with the best possible surgical experience, while at the same time ensuring the delivery of cost-effective care. The facilities at hand achieve this by saving the government, patients, and third-party payers' money. When comparing health care charges in HOPDs vs ASC throughout the country, the Medicare program, its principal beneficiaries, and related stakeholders save over $2.6 billion in benefits annually. This is because ASC reimbursement is significantly less for procedures (13). In addition, patient co-pays are concomitantly lower. Concisely, ASCs serve a significant role as the most suitable lower-cost alternative to outpatient surgical procedures.

Research on the efficiency of ASCs attributes their tremendous growth since the 1980s to the facilities' flexibility in meeting the rapidly growing demand for less-complicated outpatient surgery services. Despite their smaller footprint than HOPDs, ASCs remain less costly (10,13). First, they are less expensive to build even in urban and related environments, where vital resources such as land may be difficult to acquire. ASCs occupy minimal space, which means that their construction and general maintenance incur lower overhead costs. If the government formulated and implemented a change-driven policy that requires half of all the available procedures to be executed in ASCs, Medicare would be well positioned to save over $25 billion in the next one decade (13). In essence, all these are achievable following the benefit to insurers and Medicare from lower surgical prices in ASC settings.

Insurers, Medicare allowable rates, currently pay approximately half of the total amount paid in ASCs compared to HOPDs for performing the same surgical procedures. For instance, referring to CPT code 66982, extracapsular cataract extraction removal (ECER), Medicare pays a total of $1,671 for the surgery in HOPD, while under ambulatory payment classifications, (APCs), the program pays only $964 to ASCs for the same procedure (13). This high reimbursement gap in payment is one of the most recent discrepancies in the U.S. healthcare payment system. If the reimbursement gap of ASCs and HOPDs were only 16%, by 2017 the payment to HOPDs would have been approximately 82% more than ASCs (2).

Patients pay less for surgical procedure coinsurance done under ASCs than for those under HOPDs (percentage of payment rate). Therefore, Medicare beneficiaries end up paying $496 in coinsurance when they go through an ECER in an HOPD versus the $195 in ASCs (13). Without the introduction of ASCs, it is evident that healthcare expenditures in the U.S. would be amounting to hundreds of billions of dollars. As most private insurance companies use Medicare allowable reimbursement as a principle in reimbursement, the same rate of saving would apply. For this reason, employers benefit from reduced healthcare expense because employees embrace ASC services over HOPD services (14). Therefore, in theory, health care cost savings should be reflected by decreasing insurance premiums. This would financially benefit both the employee and the employers.

The wide gap between the reimbursement of ASCs and HOPDs plays a central role in threatening the various gains directly attributed to performing surgical procedures in an ASC setting. The payment differential plays a central role in creating an unsustainable market dynamic characterized by well-established hospitals strategically purchasing ASCs and converting them into HOPDs (15). This ploy of a hospital to convert an ASC into a HOPD that is located remotely, can result in higher medical costs. This occurs because once an ASC is acquired by a hospital, its ASC license can be terminated and converted into one of the hospital's units. This newly acquired unit will bill surgical procedures to the HOPD rates rather than ASC rates. As a result, the ASC will bill patients at higher rates.

Patient Satisfaction

Results obtained from recent surveys, studies, and systematic reviews show that patients are satisfied with the services and care they receive from ASCs. In particular, the majority of patients under ASC programs tend to cite reduced or lower costs, the ease involved in operation scheduling, the provision of safe and quality services, transparency, and increased personal attention as the main reasons for embracing ASCs (2). The ASC industry acknowledges and appreciates the important role played by disclosing pricing information in client satisfaction and overall loyalty (16). By making information about pricing available before surgery, ASCs promote transparency among all patients and Medicare beneficiaries. For the benefit of consumers, these disclosures set out the total price for the intended surgical procedures and specify the payment terms. By doing so, they empower healthcare consumers by providing the best opportunity to evaluate costs and compare prices among different healthcare providers. The U.S. ASC health care delivery model comprises of convenience, efficient care, and patient satisfaction. It revolves around enhancing patient care by enabling physicians and other practitioners to focus exclusively on small-scale processes in single settings rather than relying on hospital settings that typically have large-scale demands for the management's attention, space, and resources (16). With the limited number of surgical rooms and space, physicians can intensify quality control to ensure effectiveness in ASC processes. Additionally, the change-oriented and holistic model allows patients to gain quick access to their physicians, bringing concerns directly to responsible physician operators, particularly those that have direct knowledge about their cases. In essence, the three-dimensional framework adopted by ASCs improves customer satisfaction by reducing bureaucratic procedures usually encountered when dealing with various hospital administrators, who have less detailed knowledge about specific patients and their experiences.

ASCs can create and maintain physician ownership, which may help promote their presence in the health care market. As an extension of their practice, ASCs may allow physicians to increase the types of cases performed in these centers. This will ultimately reduce the patient wait-times for the procedures. In this way, ASCs encourage further specialization in the ambulatory setting. Unlike large-scale health institutions, such as hospitals, ASCs place greater emphasis on providing quicker, more responsive environments tailored to meet the changing individual needs of patients. With this lower bureaucratic system, ASCs enable physicians to exercise increased control over scheduling (17). As a result, the model decreases delays before or after performing given procedures. In hospital settings, physicians often delay or reschedule some surgical procedures following an institutional demand, including attending to emergencies. Unforeseen emergency room demands hinder practitioners' productivity and concomitant increase health care costs because patients are compelled to wait for many days before the operation or to leave the facility (17). Ultimately, physician ownership in ASCs allow surgeons to implement innovative strategies for leadership, governance, and quality improvement.

Patients identify ASCs and report improved satisfaction levels because the outpatient surgical facilities remain committed to quality. In fact, quality-care serves as one of the important hallmarks of ASC health care delivery model (5). The ASC community continues to show its commitment to offer quality collaboration through the ASC Quality Collaboration (AQC). The latter is an independent and transformation-driven initiative meant to promote safety and quality in ASCs. Tasked with the responsibility of developing meaningful and realistic quality measures for various ASC settings, AQC further oversees voluntary reporting by ASCs, ensuring accountability for the sake of the patients. A typical case in point involves the organization's

role in urging the Center for Medicaid Services (CMS) to focus on establishing standardized, comprehensive, and uniform quality and accountability reporting systems. Briefly speaking, the primary purpose of such systems would revolve around financial management, social responsibility, and performance. Accordingly, the already formulated quality measures aligned with the U.S. national plan goals, which revolve around transparency and healthcare cost reduction.

Apart from quality commitment, patients treated in ASCs tend to fare better than their counterparts who were operated in HOPDs. Using variations in ASC generated by the ongoing changes in APCs and Medicare reimbursements, Stone et al. (5) collected data on the safe surgery checklist and volume of procedures to determine patient satisfaction levels in selected HOPDs and ASCs. Considering the likelihood of patients who have undergone any of the highest-volume outpatient surgical procedures in an ASC or HOPD to visit EDs or have physicians operate them again, the researchers recorded patient outcomes. The highest-risk patients under Medicare program were less likely to visit EDs or be admitted to hospitals after having their surgeries performed in ASCs as compared to their high-risk Medicare counterparts treated in HOPDs5. At the same time, the researchers' satisfaction survey with an 85.7% response rate showed that 91.7% of patients reported happiness for going home in the immediate aftermath of their operations (5). Approximately, 96% reported additional confidence because they could exercise more control over their lives and funds during and after treatment. Undoubtedly, these findings serve as a clear indication that ASCs provide the much-needed quality care, regardless of patient's vulnerability levels.

Physician Satisfaction

Physicians developed ASCs in response to a myriad of challenges in their traditional hospital workplace, where they could not achieve the desired satisfaction levels. Besides complaints from patients who could wait for several days before receiving the recommended surgical services, medical professionals tasked with the responsibility of executing surgeries encountered and had to deal with slow and cumbersome operating turnover times, the inability to obtain new equipment due to poor, ineffective hospital policies and budgets, and frustrations involving scheduling delays (13). Even though Medicare has proved less receptive of these ASCs, individual physicians are quick to adopt and integrate technological advances in their operations, mainly by starting joint ASCs (16). This way, their morale has since reached an all-time high, while at the same, helping patients, including Medicare beneficiaries.

The ability of physicians to utilize new technologies to perform a growing range of simple to complex range of procedures safely on an outpatient basis not only show that they enjoy their work but also utilize their skills and potential. For example, physicians in the present-day society are now well-positioned to accomplish their operations within the shortest possible time because they employ the use of effective and less invasive techniques. Some of these new and result-oriented technologies include advanced anesthetics and endoscopic procedures (13). Traditionally, complex and multifaceted procedures needed long hours to complete, required physician operators to use major incisions, long-lasting anesthetics, as well as extended convalescence. The new approach employs the use of short-acting anesthetics and involves shorter recovery times. In other words, physicians no longer spend protracted follow-ups to ensure complete recovery from surgical procedures. All these advantages have far-reaching economic value because surgeons can maximize their talents, the government spends relatively less on health reimbursements, and patients remain well positioned to develop a quicker recovery in ASC settings.

The efficiencies attributed to ASCs revolve around the facilities' role in creating high-level flexibility among physicians. The disparities witnessed in recovery and preoperative times determine the differences in satisfaction and motivation levels between ASC and HOPD surgeons (1). Compared to the prevailing situations in HOPDs, for instance, ASC physician operators are more likely to operate from a single and strategically located facility. Since this location serves as their working point for multiple cases, the surgeons are in the best possible position to minimize delays (15). The small size and strategic location of ASC facilities reduce travel time wastage and increase physician productivity; thus, minimizing overall overhead costs that could be incurred in a complex hospital setting with many buildings and departments.

The turn-over time in operating rooms in ASCs remain significantly shorter than in HODPs because teams of staff typically have more consistent and clear roles. Though hospital surgery departments are often organized in a systematic and proper manner, the presence of many employees, activities, and patients with a variety of needs play a central role in making physicians less productive and satisfied in the workplace (12). In contrast to employees in HOPDs who tend to work in shifts, staff members in ASCs usually have incentives to accomplish their duties quickly, leading to higher teammate satisfaction. On the other hand, hospitals tend to re-operate as well as add-on cases, which directly compete with planned and potential outpatient procedures, causing fatigue and decreased employee morale. The economic theory provides that favorable work environment in an organization is inextricably linked to satisfied employees, who often align their objectives with the already established organizational goals (16). It means that physicians working in an ASC remain committed to the whole process of holistic benefit maximization, while at the same time contributing toward the concerted effort aimed at minimizing health care costs both at the national and facility levels.

In addition to conducive work environments and timely execution of surgical procedures, ASCs contribute to increased physician satisfaction because of the ownership principle. Essentially, physicians with ownership stakes in a given ASC usually enjoy greater profits when and after performing procedures in such facilities rather than HOPDs (9,15). Individual physician's professional reimbursement is not linked to site of technical service. Physicians may share profitability of an ASC with ownership opportunities. Although some critics argue that this practice may lead to demand inducement, with some providers recommending unnecessary and risk-laden procedures in their ASCs, the government has strict quality laws in place, governing the operation of physician-owned ASCs (17). ASCs must be linked to group practice models or be an extension of the surgeon's practice. In essence, reduced operation costs benefits patients and physicians alike.

Physicians draw their satisfaction from the freedom involved in the decision-making process. As stated earlier, ASCs differ from hospital-based outpatient surgery centers because a group of individual physicians owns the facilities; they are empowered with the opportunity to opine on crucial decisions (9). For example, physicians have to decide on which patients to treat at HODPs versus an ASC. The decision to operate a given patient at their ASCs may be driven by convenience, fulfilling amenities, greater flexibility with regard to scheduling procedures, and setting's efficiencies.

Physician-owners often consider economic, social, and non-economic factors when making vital decisions regarding whether to operate and treat given patients at their ASCs. A physician may choose to maximize their profits by treating a patient whose profit margin surpasses that of other patients with planned surgeries (15). In as much as this decision may be perceived negatively by opponents of

ASCs, proponents strongly argue that profit maximization alongside desirable patient outcomes conform perfectly well to the welfare agenda of any health care system16. For example, the act of treating the most at-risk patients for life-threatening complications at HOPDs involves optimizing better resources found in hospitals. Ultimately, recent studies have concluded that the differences between HODPs and ASCs suggest that hospitals can only maximize on their efficiencies and physician satisfaction by adopting highly specialized and unique organizational models.

Criticism

The profitability associated with ambulatory surgical procedures continues to place the image of ASCs in bad light. Critics argue that some physicians are neither driven by patient well-being nor overall healthcare reduction costs, but by their self-interests (17). In particular, this school of thought argues that the concept of physician ownership has since made ASC operations a business affair in which individual physicians place great emphasis on maximizing their income. Physicians receive the facility's fee share when their patients pay the ASCs. Since they typically receive nothing when such patients pay the HOPD, physicians may resort to hijacking patients that are more profitable, treating them in their own ASCs. This behavior could have adverse effects on the profitability of HOPDs and general hospital revenues. One of the Missouri-based hospitals, St. Louis, recently reported a significant drop in their annual revenue by more than 23% (17). The administrator cited an ASC near the hospital as the cause of the loss. The practice remains a major problem because many hospitals subsidize a number of healthcare services offered in their departments, such as uncompensated and charity care.

The incentive problems attributed to physician ownership of an ASC tend to have adverse effects on a healthcare facility's efficiency. For example, inefficiencies may be witnessed in health care delivery if physicians choose to assign patients to particular ASCs or HOPDs for profitability purposes, not patient needs (15). Anecdotal evidence suggests that ASCs have a negative impact on the financial performance of hospitals.

Conclusively, it is evident that patient clinical outcomes as well as patient and physician satisfactions justify the potential economic advantage of undertaking surgical procedures in ASCs rather than HOPDs. The expanded health insurance coverage in the U.S. has presented policymakers and related stakeholders with opportunities to identify and explore change-driven ways through which the country would accommodate the rapidly increasing demand for outpatient surgical services, compelling individual physicians to create ASCs. Serving as the immediate alternative to hospital-based outpatient surgeries, the ASCs were established with the sole purpose of improving health care quality and reducing health care costs by either eliminating or minimizing reoperation and infection rates. ASCs remain economically beneficial for many reasons. In particular, the facilities play a central role in creating high-level flexibility among physicians. Patients typically pay far less coinsurance for surgical procedures done in the ASC setting than for similar procedures undertaken in the HOPD. Additionally, insurers in collaboration with Medicare currently pay approximately half of the total amount paid in HOPDs for performing the same surgical procedures. Referring to CPT code 66982, extracapsular cataract extraction removal (ECER), for instance, Medicare pays a total of $1,671 for the surgery in HOPDs, while under APCs the program pays only $964 to ASCs for the same outpatient procedure. In essence, the overall economic benefits in a free market system attributed to ASCs revolve around efficient and flexible physician practice, the cost savings, patient satisfaction, high-level quality care.

References

1. Munnich EL, Parente ST. Procedures take less time at ambulatory surgery centers, keeping costs down, and ability to meet demand up. ***Health Affairs*** 2014;**10(5)**: 764-9.
2. Ambulatory Surgery Center Association (ASCA). ASCs: A Positive Trend in Health Care. Available from: https://www.ascassociation.org/advancingsurgicalcare/aboutascs/industryoverview/apositivetrendinhealthcare
3. Toy P, Fournier MN, Throckmorton TW, Mihalko WM. Low rates of adverse events following ambulatory outpatient total hip arthroplasty at a freestanding surgery center. ***The Journal of Arthroplasty*** 2018;**33(1)**:46-50.
4. Centers for Medicare & Medicaid Services. CMS Issues 2017 Final Hospital Outpatient and ASC Rule: A Summary for Spine Surgeons. Available from: http://www.isass.org/awp/wp-content/uploads/2016/11/Final-2017-OPPS-and-ASC-Rule-Summary-3.pdf
5. Stone MA, Singh P, Rosario SL, Omid R. Outpatient total elbow arthroplasty: 90-day outcomes. Journal of Shoulder and Elbow Surgery 2018;**27(7)**:1311-6.
6. Owens PL, Barrett ML, Raetzman S et al. Surgical site infections following ambulatory surgery procedures. ***Journal of the American Medical Association*** 2014;**311(7)**:709-16.
7. Uppal G. Orthopedic Surgeon. Personal Communication. 26th March 2018.
8. Olsen MA, Tian F, Wallace AE et al. Use of quantile regression to determine the impact of total health care costs of surgical site infections following common ambulatory procedures. ***Annals of Surgery*** 2017;**265(2)**:331-9.
9. SCA. SCA Teammate Pulse Survey. 2017.
10. Grisel J, Arjmand E. Comparing quality at an ambulatory surgical center and a hospital-based facility: Preliminary findings. ***Otolaryngology Head and Neck Surgery*** 2009;**141(6)**:701-9.
11. Hughes RG, (ed.). Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Available from: https://www.ncbi.nlm.nih.gov/books/NBK2651/. providers/resources/nursing/resources/nurseshdbk/nurseshdbk.pdf
12. Vila H, Soto R, Cantor AB, Mackey D. Comparative outcomes analysis of procedures performed in physician offices and ambulatory surgery centers. ***Archives of Surgery*** 2003;**138(9)**:991-5.
13. Burke C. ***The challenge of financing healthcare: Provider impressions from a decade-long journey***. [Presentation] Healthcare Association of New York State. 24th May 2018.
14. Ohsfeldt RL, Pengxiang L, Schneider JE et al. Outcomes of surgeries performed in physician offices compared with ambulatory surgery centers and hospital outpatient departments in Florida. ***Health Service Insights*** 2017;10:1178632917701025.
15. 15) Plotzke M, Courtemanche C. Does procedure profitability impact an outpatient surgery is performed at an ambulatory surgery center or hospital? ***Health Economics*** 2011;**20(7)**:817-30.
16. 16) Bernell S. ***Health economics: Core Concepts and Essential Tools***. Chicago, USA: HAP/AUPHA/Health Administration Press; 2016.
17. 17) Feldstein MJ. As Outpatient Centers Vie with Hospitals for Income, Patients Seem Caught in the Middle. ***St. Louis Post-Dispatch*** 2006:A1.

The Implication of Music Therapy on the Anxiety of Patients Undergoing Day Surgery with Non-General Anaesthesia

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Abstract

Purpose: To investigate the implication of music therapy on the anxiety of patients undergoing day-surgery with non-general anesthesia.

Methods: 90 patients ranging from October 2016 to November 2016 in Changzheng Hospital were enrolled in our study. They were classified into two groups with each having 45 cases. One received music therapy perioperatively, while the other did not. Analysis was made to evaluate the anxiety difference between two groups.

Results: The anxiety degree of the control group was inferior to the test group, according to the ST-AI condition.

Conclusion: During the whole procedure, patients suffered from different anxiety degree, and attained nervousness relief through music therapy, then they could make better cooperation with doctors, relieving postoperative pain. Therefore, music therapy deserves to be recommended in the clinical nursing practice.

Key Words: Music therapy, Day-surgery, Non-general anaesthesia, Anxiety.

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Introduction

In countries like America and Canada, the amount of day-surgery accounts for 90% of the total number, and in European countries the percentage also reaches over 80% [1]. In 2003, The International Association surgery (IAAS) defined day-surgery as the following: surgery is conducted on the day of admission, and patients are dischargedon the same day, except the minor surgeries in the outpatient way or clinics [2]. Recent years has witnessed the growing attention on day-surgery, which aims at cutting down the time in hospital and decrease the medical cost. Higher demands are posed on both hospital and medical employees in order to promise the same effects for patients receiving day-surgeries with those in hospital. Actually we find the fast and frequent process is a kind of severe mental stimulation, such as nervousness, fear, anxiety, etc, which affects the surgical process and the outcomes with a great extent [3], especially the anxious emotion caused by consciousness during the operation. Music therapy was established as a subject since 1944 in Michigan University, and has developed as a mature integrated subject [4]. Previous research has showed that listening to music could change the physical and psychological status, help produce positive reactions, coordinate our physical activities, eliminate the nervousness, relieve the negative emotions, such as agitation and anxiety [5]. We chose the proper patients undergoing non-general anesthesia and observe the changes of their anxiety and depression.

Materials and methods

Basic data

90 patients receiving non-general anesthesia were enrolled into the study from October to November in 2016. The patients were divided into observational and control groups randomly. The age ranged from 16 to 77 years old. The methods of anesthesia included 39 local, 45 lumbar and 6 brachial plexus anesthesia. No statistical significance was found in basic data between two groups.

Methods

Control group: patients received regular preoperative education. Through fast and effective communication, the doctor and nurse introduced the treatments and the attentions during the operation, in order to make patients feel safe and believe in the medical workers.

Observational group: during waiting the operation room, besides the measures above, special music were played according to the psychology professor's advice and personal tastes throughout the whole surgical procedure.

Evaluation standard

We investigated the anxiety degree via ST-AT questionnaire. S-AT is a scale for condition, and T-AI is a scale for anxiety.

Statistics

All statistics were performed using SPSS 13.0, quantitative data was recorded using mean and standard deviation, t test or variance analysis was adopted to judge the difference. Enumeration data was tested using x2 test. $p<0.05$ was considered statistically significant.

Results

Before the operation, no statistical significance was found in T-AT between groups (32.26 ± 5.23 vs. 40.91 ± 8.61). while the S-AT in observational group is obviously inferior to that in control group with $p<0.05$ (40.06 ± 3.14 vs $.41.22\pm6.36$).

After the surgery, statistical significance was also found in T-AI between groups (38.46 ± 7.42 vs. 42.63 ± 7.91).

Discussion

Causes of day-surgery related anxiety: Clinical studies show that the patients all have anxiety to a different extent and reach the peak at the 15-30 min before anesthesia or the morning of surgery [4]. Day-surgery is a newly developed medical model for which there is still no standard definition. According to the available studies and practice, it is generally recognized that day-surgery is the whole process of admission, receiving surgery and discharge [6]. Surgery is actually a strong stimulus for patients, usually resulting in adverse effects such as fear and anxiety [7]. Through negotiation, patients are usually lack of the recognition of surgery, and worry about the post-operative

pain, complications and prognosis due to the short time of hospital stay. Music therapy is kind of natural customized treatment to help the patients reach the balance of physic and emotion, via providing the individual music types [8].

The importance of preoperative music therapy is to relieve the nervousness, with the relevant study [9] demonstrating that harmonious music can enable the patients to keep the stable respiratory frequency, heart rate and blood pressure. It also helps to distract one's attention and the doses of the analgesic and tranquilizer. There are also studies [10] reporting playing music before the operation had gained best outcomes, better than that during the procedure and after the surgery. And the effect could get better if we communicated and educated the patients including the rules and the security systems in cases of complications. Music therapy increases the cooperation between patients and doctors, playing music during the process can regulate the function of brain limbic system and reticular structures. The pleasant rhythm can improve the mental health and distract attention, making patients relax by relieving nervousness and anxiety [11]. With the rapid development of our medical area, a number of newly-developed nursing methods has been applied in the clinical practice. Music therapy, as one of them, is good to relieve the nervous emotion, decrease the anxiety and improve the mental condition. The music rhythm with certain frequencies can better coordinate the different organs to produce the pleasant sensation, to relax the nerve movement, and promote the excitability of the cerebral cortex. It also activates the subcortical autonomic nerves to sustain the emotion, eliminate nervousness, cooperate the different systems, decrease the mental pressure and keep energetic and focussed. Besides, the doctors and nurses can also enjoy the pleasant music [12]. Therefore, music therapy deserves to be recommended in the day-surgeries.

References

1. Song jin Huang Ruchun. Several considerations for the construction and operation management of hospital daytime operating room[J] ***Day Surgery Room Construction*** 2016; 07.
2. Yu Deliang Ning Pengtao, Wang Juan Liu Xiaonan Thoughts on the definition of day surgery and the first recommended surgery for surgery [J]2015,12;539
3. Xie Mingliang Therapeutic effect of music therapy on anxiety and depression in surgical patients [J] ***Chinese Medicine Guide*** 2014:**12(11)**234-235.
4. 4Xu Jingying Li Chen Research on the psychotherapy of music [M] ***Art Science and Technology.***
5. Gao Qingqin Chen Lihong Xie Yunfei Application of relaxing music in quality nursing services in primary hospitals [J] ***Chinese Medicine Frontier*** 2012:**01(7)**;67.
6. Deng Lingling Application of Music Nursing in Outpatient Operating Room [J] ***Nursing Research*** 2012:**12**;(34).

1.

7. Jiang Shengqiu Xu Liyu Huang Feixiang Several problems that need to be clarified in the development of day surgery in China [J] ***Medicine and Society*** 2015:**11(28)**;5.
8. Su Jinhua Exploring the effect of preoperative visit on anxiety in patients undergoing elective surgery [J] ***Clinical Nursing*** 2016:**11**;(21).
9. Jiang Jieshan Feng Liuming Deng Yingfeng Zheng Jiejun Clinical nursing observation of background music therapy in operating room nursing[J] ***Inner Mongolia Traditional Chinese Medicine*** 2015:**06**;178.
10. Wang Jin Lian Guijun The role of music in operating room nursing [J] ***Chinese Medicine Emergency*** 2006:**10(15)**;1180.
11. Public Medicine [M] ***Scientific Life*** 77.
12. Dong Shuqin, Zu Yan, Zhang Jianfeng, Wang Shuang. Application of light music intervention in artificial femoral head prosthesis replacement [J] ***Today Nurse*** 2009:**10(10)**;46.

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