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Stapled haemorrhoidectomy in Chinese patients: a prospective randomised control study

以吻合器痔瘡環狀切除術治療華裔病者：前瞻性的隨機對照研究

Objective. To compare stapled haemorrhoidectomy with open diathermy haemorrhoidectomy in Chinese patients with respect to the postoperative pain, symptom control, and manometric alterations.
Design. Prospective randomised controlled trial.
Setting. A regional general surgical unit, Hong Kong.
Patients. Twenty-four patients with second- or third-degree haemorrhoids or who have had failed medical treatment.
Intervention. Open diathermy haemorrhoidectomy or stapled haemorrhoidectomy.
Main outcome measures. Structured questionnaire for symptoms, anorectal manometry, transrectal ultrasound, and postoperative pain.
Results. Stapled haemorrhoidectomy compared with open diathermy haemorrhoidectomy resulted in similar postoperative pain and drug requirements. Postoperative control of prolapse symptoms was significantly better with open diathermy haemorrhoidectomy than with stapled. The control of other symptoms was similar with regard to bleeding, pain, pruritis, and incontinence scores. Anorectal manometry showed a decrease in the maximum resting pressure and maximum squeeze pressure in both groups, but the decrease was only significant in the stapled haemorrhoidectomy group.
Conclusions. Stapled haemorrhoidectomy is as effective as conventional haemorrhoidectomy for the treatment of haemorrhoids, but with the exception of skin tag prolapse. There is a need for long-term follow-up for the changes in manometric parameters after haemorrhoidectomy.

目的：以術後疼痛、症狀控制以及測壓變化情況，對華裔病者進行透熱療法和吻合器痔瘡環狀切除術作比較。
設計：前瞻性隨機對照測試。
安排：分區醫院普通外科部門，香港。
患者：24 名患有第二或第三期痔瘡，或之前治療失敗的病人。
療法：透熱療法或吻合器痔瘡環狀切除術。
主要測量結果：以結構式問卷調查徵狀、肛門直腸測壓、經直腸超聲檢查，以及術後疼痛程度。
結果：接受透熱療法和吻合器痔瘡環狀切除術的病人，術後疼痛和施用藥物的情況相似。在術後脫垂徵狀的控制方面，透熱療法的治療效果明顯較佳；在控制其他徵狀如出血、疼痛、瘙痒、失禁等方面，兩組病人並沒太大分別。肛門直腸測壓顯示，兩組病人的最高靜止壓和最高擠束壓都有所下降，但只有接受吻合器痔瘡環狀切除術的病人方見顯著下降。
結論：以吻合器痔瘡環狀切除術治療痔患，與傳統的透熱療法同樣有效，但在皮膚乳頭狀瘤脫垂控制方面，則以透熱療法的效果更佳。長期隨訪以觀察切除痔患後測壓參數的變化亦是必需的。

Key words:
Hemorrhoids;
Pain, postoperative;
Surgical stapling;
Manometry

關鍵詞：
痔瘡；
疼痛，術後；
釘式縫合；
測壓法

Hong Kong Med J 2004;10:373-7

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This study has received a grant from the Tung Wah Group of Hospitals Research Fund (research project).

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Introduction

Stapled haemorrhoidectomy has gained acceptance as an alternative surgical procedure for the treatment of haemorrhoids. Randomised controlled trials have

demonstrated that stapled haemorrhoidectomy results in considerably less pain, allows an earlier return to work, and minimal morbidity at short-term follow-up.[1-5] Chinese patients seem to have a higher pain threshold possibly because of ethnic differences, and they tend to require less postoperative analgesics.[6] However, the small build of the Chinese patients may be prone to anal sphincter injuries caused by introduction of a 33-mm stapler. This article examines the advantages of stapled haemorrhoidectomy over open diathermy haemorrhoidectomy with regard to postoperative pain, symptom control, changes in anal sphincter manometry, and ultrasound.

Methods

Between June 2001 and May 2002, 24 consecutive patients who had either second- or third-degree haemorrhoids or had failed previous medical treatments were recruited into this trial. The study was approved by the hospital ethics committee, and informed consent was obtained from all the participants. Patients with acute haemorrhoidal complications including thrombosis; acute irreducible prolapse; or coexisting anorectal disease, such as fistula, fissure, or rectal prolapse; or who had prior surgical treatment for haemorrhoids, were excluded from this study.

All patients were preoperatively assessed using a structured symptoms questionnaire and by the use of the Williams incontinence score. Anorectal manometry evaluation was performed using a water perfusion catheter (Zinetics Anorectal Manometric Catheter; Medtronics, Skovlunde, Denmark). The parameters assessed include the anal canal length, high pressure zone length, maximum resting pressure, maximum squeeze pressure, volume of first sensation, volume at first urge, and maximum tolerable volume. Endoanal ultrasound was performed using a 10-Hz endoanal probe (B-K Medical, Standtoffen, Denmark) to determine any preoperative anal sphincter injury. Both the manometry and endoanal ultrasound were performed by an experienced doctor.

Preoperative rectal cleansing was performed in all patients using a phosphate enema (Fleet; CB Fleet Company Inc, Virginia, United States) with cefazoline and metronidazole antibiotics. All operations were performed under general anaesthesia with the patient in the jack-knife position by two experienced colorectal specialists. After anaesthesia, the patients were randomly assigned into either open diathermy (open group) or stapled (stapled group) haemorrhoidectomy groups using a sealed envelop method.

The open diathermy haemorrhoidectomy used a Pratt's bivalve speculum. External and internal components were excised by diathermy to the apex of the haemorrhoids above the dentate line. Three haemorrhoids were removed in each of the patients. The wound was left open to granulate and no postoperative packing was applied to the anus.

Stapled haemorrhoidectomy was performed with the use of the PPH 33 stapler (Ethicon Endosurgery, Cincinnati, Ohio, United States). A 37-mm circular dilator was firstly introduced, and then a 2-0 Prolene purse-string suture was inserted at the submucosal layer at least 2 cm above the dentate line. A 33-mm PPH stapler was then introduced into rectum and the ends of the purse-string suture were brought out from the side-hole of the stapler. Traction was maintained on the purse-string suture so that a substantial amount of mucosal tissue was engaged by the stapler. The stapler was closed tightly and fired. After removal of the stapler gun, haemostatic 2-0 Vicryl sutures were used at any sites of bleeding.

Postoperatively, oral dologesic tablets and intramuscular pethidine (1 mg/kg) were prescribed for pain control as required. All patients were assessed daily by self-reporting of their maximal pain levels at rest and during defecation by the use of a 10-cm visual analog scale. The amount of analgesics required was also prospectively recorded by the patient on the pain assessment questionnaire. Patients were discharged home if the pain could be controlled by oral analgesics, when no complications were found, and when they felt confident enough to be discharged.

All patients were reassessed at week 8 after the operation using the same structured symptoms questionnaire, anorectal manometry, and endoanal ultrasound. A single experienced doctor, who was not made aware of the previous method of the operation, performed both the manometry and ultrasound.

The Student's *t* test and the paired *t* test were performed on the continuous variables and the Mann-Whitney *U* test was performed on non-parametric variables as appropriate. A probability of <0.05 was taken as statistically significant. The sample size of 24 was calculated based on a 50% reduction in postoperative pain with a power of 80% at 5% significance.

Results

The demographic data and symptoms of the open and stapled groups at presentation are shown in Table 1. There was no significant difference between either group. The operative results are shown in Table 2. One patient in the open group developed urinary retention and required catheterization for 1 day. None of the patients developed postoperative bleeding, and the median postoperative stay for the stapled group was significantly shorter than the open group. The mean and maximum pain scores at rest for the first 2 days were similar for both groups. The maximum pain score on defecation was also similar. No significant differences were observed in the total amounts of analgesics required for both groups, either orally or parentally (Table 3). The proportion of patients with improvements in symptoms, such as bleeding, pain, and pruritus was also similar between the open and stapled groups. In contrast,

Table 1. Demographic data and symptoms at presentation

Characteristic	Patient group		P value
	Open	Stapled	
Mean age (standard deviation) [years]	51.9 (11.5)	46.2 (12.2)	0.26*
Sex (male/female)	6/5	5/8	
Symptoms (male/female)			
Bleeding	7/11	10/13	0.29†
Second-degree prolapse	5/11	8/13	
Third-degree prolapse	3/11	3/13	0.24†
Fourth-degree prolapse	3/11	1/13	
Pain	5/11	4/13	0.56†
Pruritus	1/11	5/13	0.08†
Incomplete defecation	5/11	7/13	0.32†

* Student's *t* test
† Mann-Whitney *U* test

Table 3. Postoperative pain scores*

Characteristic	Patient group		P value‡
	Open Median (IQR†)	Stapled Median (IQR)	
Overall pain score for the first 2 days	3.1 (2.0)	4.0 (3.8)	0.931
Maximum pain score at rest for the first 2 days	4.7 (3.4)	5.1 (7.0)	0.622
Maximum pain score on defecation	3.7 (5.2)	5.4 (3.4)	0.220
Dologesic tablets required	8.2 (17.3)	8.2 (15.5)	0.340
Pethidine, total (mg)	0 (15.0)	0 (67.5)	0.542

* Visual analog scale is used for measurement
† IQR interquartile range
‡ Mann-Whitney *U* test

Table 2. Operative results

Characteristic	Patient group		P value*
	Open	Stapled	
Median operation time (IQR†) [min]	30 (15)	35 (7.75)	0.26
Median hospital stay (IQR) [days]	2 (1)	1 (1)	0.014
Complications:			-
Urinary retention	1	0	
Postoperative bleeding	0	0	

* Mann-Whitney *U* test
† IQR interquartile range

Table 4. Symptomatic improvement after operation

Characteristic	Patient group		P value*
	Open	Stapled	
Bleeding (% improved)	45%	62%	0.924
Prolapse (% improved)	100%	62%	0.003
Pain (% improved)	45%	31%	0.366
Pruritus (% improved)	18%	31%	0.149
Williams incontinence score (% improved/static)	100%	100%	0.277

* Wilcoxon test

Table 5. Manometry changes

Characteristic*	Patient group	Preoperative Mean (SD)	Postoperative Mean (SD)	P value†
Anal canal length (mm)	Open	52.2 (11)	50.1 (7)	0.252
	Stapled	50.5 (5)	46.5 (5)	0.108
HPZ length (mm)	Open	30.2 (8)	28 (6)	0.301
	Stapled	31.6 (7)	32.5 (5)	0.654
MRP (mm Hg)	Open	94.7 (25.7)	85.2 (31.5)	0.232
	Stapled	117.1 (31.9)	84.9 (13.8)	0.007
MSP (mm Hg)	Open	164.0 (45.8)	139.4 (34.9)	0.023
	Stapled	149.7 (39.2)	117.2 (33.4)	0.040
Vol FS (mL)	Open	97.2 (13.7)	88.9 (33.1)	0.310
	Stapled	115.8 (35.4)	99.7 (39.8)	0.344
Vol FU (mL)	Open	144.1 (22.5)	117.1 (32.2)	0.071
	Stapled	173.1 (35.6)	143.3 (43.9)	0.038
MTV (mL)	Open	186.7 (32.0)	155.1 (20.8)	0.025
	Stapled	219.5 (53.3)	172.2 (52.1)	0.012

* HPZ denotes high pressure zone, MRP maximum resting pressure, MSP maximum squeeze pressure, Vol FS volume of first sensation, Vol FU volume at first urge, MTV maximum tolerable volume
† Paired *t* test

better symptomatic improvements of skin tag prolapse were noted in the open group (Table 4). None of the patients in either group complained of any deterioration of continence as indicated by the incontinence score.

Preoperative anorectal manometry showed that there was no significant difference in anal pressure and rectal volumes between the two groups. A decrease in postoperative maximum resting pressure and maximum squeeze pressure was found in the anorectal physiological examination in both groups. The decrease in maximum resting pressure was significant in the stapled group but not in the open group (Table 5). The presence of internal anal sphincter muscle fibres was found according to the pathology reports

in nine out of 11 patients in the open group and eight out of 13 patients in the stapled group. This finding was not statistically significant. No internal anal sphincter disruption was detected on postoperative transanal ultrasound in any of the patients. A decrease in all the rectal volumes was also noted in the postoperative anorectal physiological examinations.

Discussion

Published randomised controlled trials and a recent review by the Australian Safety and Efficacy Register of New Interventional Procedures-Surgery showed that stapled haemorrhoidectomy produced similar symptom control[3,5,7,8] when compared with open diathermy haemorrhoidectomy, but was found to produce less postoperative pain.[1,3-6] This current study is unique because it explored the benefits of stapled haemorrhoidectomy in Chinese patients and takes into account the cultural differences in the perception of pain and the physical build.

The type of postoperative pain is different between the two procedures and the use of the visual analog scale both at rest and during defecation is well accepted for such assessments. For diathermy haemorrhoidectomy, the pain is sharp and tearing, whereas for stapled haemorrhoidectomy, it is vague, dull, and tenesmoid.[9] In contrast, this study did not show any significant differences in terms of the postoperative pain between the two groups of patients in the early postoperative period. The amount of pain experienced by the patients for either procedure was low and well tolerated. The presence of an open wound during the healing period did not result in much pain. This low pain experienced in both procedures could be because of the ethnic differences in pain perception but this needs to be verified. Nevertheless, this study showed that stapled haemorrhoidectomy conferred no advantage over diathermy haemorrhoidectomy in terms of postoperative pain control.

The difference in the duration of hospital stay between the two procedures was not related to the pain, but because of the presence of the open wound in the conventional haemorrhoidectomy. Patients expressed concern for the management of the open wound at home and were less confident to be discharged home. The absence of a perianal wound and minimal postoperative pain make stapled haemorrhoidectomy an attractive procedure for day surgery. A recent paper has shown that stapled haemorrhoidectomy is a feasible and safe procedure to be performed as day surgery.[10]

This study showed that the resolution of skin tag prolapse, at least up to 8 weeks postoperatively, was significantly better in open diathermy haemorrhoidectomy than in the stapled group. Ho et al[2] proposed that interrupting the superior haemorrhoidal vascular supply in stapled haemorrhoidectomy resulted in the external prolapsed skin tags shrivelling during the postoperative period, which was seldom perceived as a problem by their patients. It is understandable that open diathermy haemorrhoidectomy will produce an immediate and substantial reduction in skin tag prolapse. Conversely, the efficacy of skin tag shrivelling after stapled haemorrhoidectomy is less predictable and may need further investigation. Because skin tag prolapse may be one of the main indications for surgery, the difference found in this study will influence the choice of operation for those with such a symptom.

Evidence of sphincter injury after transanal stapling for colorectal cancer surgery has been reported and the use of an even larger (37-mm external diameter) anal dilator in stapled haemorrhoidectomy has raised genuine concern. Continence assessment was one of the secondary end-points in a few published randomised controlled trials.[1-3] Despite this risk, none of the published trials as well as this study has shown a considerable deterioration in the postoperative incontinence for either method. Clinically, continence depends on many factors including the anorectal integrity. Impairment of one of the component of the anorectal continence mechanism—for example, as a result of surgery—may be subclinical because other factors may compensate. Nonetheless, incontinence is a concern of the patient and is, therefore, of clinical relevance.

Both anal manometry and endoanal ultrasound of the anal sphincter—which are the quantitative assessment of the function and the assessment of the structural alteration, respectively—are sensitive methods of assessment for possible sphincter injury. Published data comparing preoperative and postoperative manometric assessments showed mixed results. No significant changes were noted in the majority of these trials,[1,2] but one study noted a significant decrease in postoperative pressures in the open diathermy group.[3] Conversely, a similar randomised controlled trial comparing sutured and stapled haemorrhoidectomy showed a significant decrease in postoperative sphincter pressures in the stapled group.[4] Although our study showed a postoperative decrease in both the maximum resting pressure and maximum squeeze pressure in both the open diathermy and stapled haemorrhoidectomy, it was only statistically significant in the stapled group.

The decrease in the manometry pressure may be because of structural injuries to the anal sphincter, such as a rupture or fragmentation caused by excessive dilatation or excision during the operation. A recent randomised trial reported a significantly higher incidence of sphincter fragmentation with the use of a 37-mm circular anal dilator than without.[11] The authors suggested that the risk may be reduced by avoiding the use of a circular anal dilator in stapled haemorrhoidectomy. The inclusion of internal anal sphincter muscle[4,5,12] or even external anal sphincter muscle[4] has been reported in the excised haemorrhoidal tissue. Internal anal sphincter muscle was also found in some excised specimens from both procedures in our study. None of the studies showed that the presence of sphincter muscle in the excised specimen had any effect on the continence or anal

manometry. Quantifying the presence of internal anal sphincter muscle in the excised specimen is extremely difficult, and we have not attempted to do this. The internal anal sphincter is visible during dissection in open diathermy haemorrhoidectomy, but not in stapled haemorrhoidectomy, which poses a potentially higher risk of severe sphincter injury. However, the site for the potential muscle inclusion in stapled haemorrhoidectomy is probably at the distal rectum, where the high pressure zone is likely to be spared, rather than in the anal sphincter.

There are only very few published reports on the long-term outcomes of the stapled haemorrhoidectomy procedure.[12,13] The changes in postoperative anal manometry cannot be explained by the excision of sphincter muscle alone. We postulate that the decrease may be caused by excessive dilatation of the anal sphincter during the procedure, but not to the extent that the sphincter fragments, which can be detected using anal ultrasound. In stapled haemorrhoidectomy, a sphincter injury would potentially be more likely than with open diathermy haemorrhoidectomy because the circular anal dilator has more of an extensive stretch, as suggested by the manometric results in this study. Because these subclinical injuries may recover or deteriorate with time, follow-up assessment in terms of clinical, ultrasonographic, and manometric parameters is urgently needed.

Conclusions

Stapled haemorrhoidectomy is an effective surgical procedure for the treatment of haemorrhoids compared with open haemorrhoidectomy, but with the exception of skin tag prolapse. Additional procedures, such as skin tag excision, may be required during stapled haemorrhoidectomy. Moreover, open haemorrhoidectomy should be considered when the indication for surgery is a skin tag prolapse. Long-term follow-up for the changes in manometric parameters after haemorrhoidectomy should also be necessary.

Acknowledgement

We would like to thank Ms Anna Tang for helping with the anorectal physiology and serving as independent third assessor.

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