Introduction

Haemorrhoids occur in up to 80% of the population, involving any age and affecting both males and females equally. They commonly occur in patients with chronic increased intra-abdominal pressure such as in chronic obstructive airway disease and in pregnancy. Symptoms of haemorrhoids include bleeding, mucosal or faecal soiling, itching and, occasionally, pain, which, if left untreated, continue to cause physical and social problems to patients. Numerous modalities and techniques have been developed to treat symptomatic haemorrhoids. Second- and third-degree haemorrhoids can be treated conveniently on an outpatient basis by means of sclerotherapy, photocoagulation, cryotherapy and rubber band ligation.
ligation, while severe prolapsed or circumferential haemorrhoids can be treated using the Milligan-Morgan haemorrhoidectomy or stapled haemorrhoidectomy.5–7

Internal haemorrhoid ligation was first introduced by Blaisdell8 in 1958 and a modified version using a rubber band was popularized as an outpatient procedure by Barron9 in 1963; the technique has remained popular, especially for second- and third-degree haemorrhoids. Initially, the recommendation was to ligate one haemorrhoid at a time in order to reduce unacceptable complications, particularly pain and bleeding.9 Multiple ligations per session, however, are safe and tolerable.10–16 The classic forceps band ligation is safe and cheap, but not without complications and requires good coordination between at least two operators for the procedure to be performed satisfactorily.

Lately, a single-operator disposable vacuum suction device has been introduced to provide convenience to both the patient and surgeon. The simplicity of this apparatus is thought to provide advantages, especially to trainee medical officers. It is generally believed that this device could reduce pain for patients and reduce the time needed to treat haemorrhoids in outpatient clinics.17 This prospective randomized clinical trial was undertaken at our outpatient clinic to compare these two methods of rubber band ligation in the treatment of second- and third-degree haemorrhoids. Pain perception during and after the procedure, intra-procedure bleeding, and other complications including residual haemorrhoids were among the variables used to compare efficacy between the two methods.

Patients and methods

This prospective randomized clinical trial took place between July 2002 and September 2003 in the surgical outpatient clinic of Hospital Universiti Kebangsaan Malaysia. All newly diagnosed patients with second- and/or third-degree haemorrhoids were included in the trial. Exclusion criteria included recurrent, fourth-degree, thrombosed or external haemorrhoids, presence of concurrent painful anal conditions, and inability to comprehend instructions or to perform the visual analogue scale (VAS) assessment.

Informed consent was obtained and patients were consecutively randomized into the forceps or suction groups. All bandings were performed by a single surgeon. With the patient in a left lateral position and knees flexed, the anus was inspected and a digital rectal examination was performed in the usual manner. A proctoscope was then inserted using a non-anaesthetic lubricant (K-Y Jelly).

In the forceps group (Figure 1), a traditional metallic proctoscope was introduced and the haemorrhoids were grasped and pulled down to their pedicles above the dentate line using conventional stainless steel forceps into the rubber band barrel for its application. This required at least two operators (the surgeon, who needed to hold the forceps in one hand and the ligator in the other hand, and an assistant, whose left hand held the proctoscope and right hand shone the light).

In the suction group (Figure 2), a self-lighted proctoscope and an LEM-disposable suction apparatus (Sapined SPA, Alessandria, Italy) were used. This apparatus was connected to a Nouvag Suction Pump set (Nouvag AG, Goldach, Switzerland). With the surgeon holding the proctoscope in one hand, using low-pressure vacuum suction, the haemorrhoid pedicles were drawn into the rubber band barrel flush on to the mucosa with the hand-gun like apparatus, which was held comfortably in the other hand. This was a single-operator procedure. Two or three columns were ligated per session.
The immediate pain score assessment and intra-procedure bleeding were recorded immediately after banding. All patients were then given a 7-day supply of paracetamol for post-procedure analgesia. They were instructed to take two tablets as required (500 mg tablets, maximum at 6-hour intervals) and to attend the casualty department whenever the pain was intolerable or any significant complications developed, especially bleeding on every bowel movement or perianal sepsis. An information sheet pertaining to the trial together with a VAS pain scoring assessment chart (0–10) were given to the patient for completion. They were then given a day-14 clinic follow-up appointment. At follow-up, a single physician, blinded to the type of instrument used, assessed pain and complications. The complications assessed were bleeding (after each defaecation or needing admission for blood transfusion) and painful defaecation at all times post-procedure until the follow-up date, tenesmus, urinary retention, perianal sepsis and residual haemorrhoids. Additional treatments were given for any complications. Pain assessments focused on the amount of pain experienced immediately, 24 hours, 7 and 14 days following the procedure. Patients were also required to disclose the total number of paracetamol tablets consumed during the 2 weeks after banding.

Ethical consideration
The trial did not deviate much from the current standard clinical practice for second- and third-degree haemorrhoids at Hospital Universiti Kebangsaan Malaysia. However, approval was gained from the research committee on the 18th June 2002 (reference: FF-40-2002).

Statistical analysis
It was estimated that the prevalence of new haemorrhoid cases was 20% of the total number of patients seen in our outpatient clinic, so the power of this study was 90% with a 95% confidence interval (CI) ± 2 standard deviations (SDs). Using SPSS version 11.0 (SPSS Inc, Chicago, IL, USA), the quantitative and qualitative variables were analysed with Student’s t test and the Chi-squared test, respectively. A p value of less than 0.05 was considered to be significant.

Results
A total of 100 patients (60 males, 40 females) were involved in the trial, 50 of whom were randomized into the suction group and the other 50 into the forceps group. There were no dropouts throughout the trial period. Ages were well distributed with an overall mean of 48.76 years (range, 15–83 years); the mean ages in the suction and forceps groups were not significantly different at 50.22 and 47.30 years, respectively (p = 0.352).

The mean number of haemorrhoids ligated per session was equally distributed at 2.42 in the suction group and 2.36 in the forceps group (p = 0.543). In assessing pain tolerance and the number of haemorrhoids ligated, we found there was no significant difference whether two or three haemorrhoids were banded in a session (Table 1). However, there was a marked difference between the two groups in pain perception immediately and 24 hours after the procedure (Table 2). The pain experienced by patients in both groups continued to decrease after 24 hours and there was no statistical difference from the seventh post-procedure day. Pain was most severe immediately after the ligation and decreased significantly after 24 hours and almost completely resolved by day 14. The mean number of paracetamol tablets used was higher in the forceps group, 4.48 tablets compared with 2.6 in the suction group (p = 0.003). This proved that more pain was perceived with classic forceps haemorrhoid banding.

Intra-procedure bleeding was significantly higher in the forceps group compared with the suction group (Table 3). Overall, 34 minor complications were observed (18 in the forceps and 16 in the suction groups) within the 2-week period following the procedure. Patients were also required to disclose the total number of paracetamol tablets consumed during the 2 weeks after banding.

<table>
<thead>
<tr>
<th>Number of haemorrhoids banded</th>
<th>2</th>
<th>3</th>
<th>p†</th>
</tr>
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<tbody>
<tr>
<td>Immediate</td>
<td>4.56 ± 2.59</td>
<td>4.62 ± 2.16</td>
<td>0.904</td>
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<tr>
<td>24 hour</td>
<td>2.62 ± 2.30</td>
<td>3.49 ± 2.11</td>
<td>0.058</td>
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<tr>
<td>7th day</td>
<td>0.74 ± 1.36</td>
<td>0.87 ± 1.38</td>
<td>0.635</td>
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<tr>
<td>14th day</td>
<td>0.23 ± 0.69</td>
<td>0.15 ± 0.54</td>
<td>0.543</td>
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</tbody>
</table>

*Data presented as mean ± 2 standard deviations; †Student’s t test.

<table>
<thead>
<tr>
<th></th>
<th>Suction</th>
<th>Forceps</th>
<th>p†</th>
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<tbody>
<tr>
<td>Immediate</td>
<td>3.08 ± 2.03</td>
<td>6.08 ± 1.78</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>24 hour</td>
<td>1.92 ± 1.93</td>
<td>4.00 ± 2.09</td>
<td>&lt; 0.001</td>
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<tr>
<td>7th day</td>
<td>0.58 ± 1.09</td>
<td>1.00 ± 2.09</td>
<td>0.125</td>
</tr>
<tr>
<td>14th day</td>
<td>0.18 ± 0.72</td>
<td>0.22 ± 0.54</td>
<td>0.755</td>
</tr>
</tbody>
</table>

*Data presented as mean ± 2 standard deviations; †Student’s t test.
after banding. These included pain at every defaecation \((n = 14)\), residual piles \((n = 19)\) and persistent tenesmus \((n = 1)\). These complications were compared between the two methods of banding, but no significant difference was found \((p = 0.673)\). There were no other debilitating complications such as urinary retention, bleeding requiring hospital admission or blood transfusion, poor anal tone or perianal sepsis. Thirteen cases of residual piles were encountered in the forceps group at follow-up compared with six cases in the suction group, but the difference was not statistically significant \((p = 0.07)\).

**Discussion**

Rubber band ligation remains one of the main modalities in treating second- and third-degree haemorrhoids. It is most convenient, least expensive and equally effective when compared with other modalities, especially when performed in the outpatient setting.\(^{18–21}\) Most banding procedures are currently performed by trainee medical officers and data comparing the two available rubber band ligation methods with regard to their complications are scarce.

In performing rubber band ligation of haemorrhoids, pain remains the main concern, although theoretically, these ligations are performed above the dentate line that is devoid of sensory nerves. During the initial years after its introduction, even a single ligation per session produced pain in 1–29% of patients.\(^9\) This was frequently observed even during careful placement above the dentate line.\(^{20}\) Furthermore, pain and anal discomfort were reported to be greater, ranging from 28% to 79%, when multiple bandings were performed per session, although the pain was reported to be eventually tolerable.\(^{22–25}\) However, recent trials have shown that multiple ligations per session are indeed safe and well tolerated and up to three haemorrhoid ligations have been performed without much discomfort in most studies.\(^{10,17,23}\) Our study similarly found that there was no significant difference in pain perception among patients who had two or three haemorrhoids ligated per session within the 2-week follow-up period. In addition, even the most severe pain could be controlled and well tolerated using oral paracetamol without the need for more potent analgesics or antibiotics such as metronidazole, as recommended by several authors.\(^{26–28}\) Pain was significantly twice as severe on the VAS when the rubber band was applied using the forceps method compared with the suction method. The most severe pain was perceived immediately after and within 24 hours of ligation in both groups. It started to disappear after 1 week and all patients were almost completely pain free after 2 weeks. This finding was supported by the amount of analgesia used, which correlated well with pain severity. Despite careful accurate placement, we found that using a forceps ligator produced more pain. The difference in pain perception remains puzzling, but we believe overzealous grasping of haemorrhoid pedicles in a less visible field could be the reason. We could not attribute this finding to any other cause than the technically cumbersome forceps apparatus.

Apart from discomfort and pain, acute complications of rubber band ligation include difficulty in passing urine and defaecation, excessive bleeding and perianal sepsis,\(^{29–31}\) while tenesmus, rectal ulcer and erectile dysfunction occur as long-term complications.\(^{30,31}\) Early postoperative bleeding occurs in about 20–40% of cases and is rarely prolonged. Improvised visual techniques such as using videoendoscopic anoscopy and the modified Barron’s technique with vacuum suction seems to reduce bleeding.\(^{30,31}\) In our study, intra-procedure bleeding occurred in 30% of patients, 25% in the forceps group. During the 14-day follow-up, no bleeding was noticed and no hospital admissions, surgery or blood transfusion was required. We attribute the significant difference in intra-procedure bleeding to the better visualization with the suction technique and the minimal physical trauma to the friable haemorrhoids and mucosal lining. Visualization is enhanced with the single-operator suction technique without the need to grasp the haemorrhoids as in the forceps technique, which in most instances will initiate bleeding. During this step of the procedure, vision may be obscured and precise placement is sometimes difficult.

Several authors have encountered perianal sepsis and faecal incontinence among debilitating complications of haemorrhoid banding.\(^{28}\) This results in poor quality of life and causes considerable morbidity.\(^{32}\) However, such complications are rare and were not observed in our study. All severe pain that occurred immediately or within 2 weeks’ follow-up was not associated with anal sphincter dysfunction or perianal sepsis. Perhaps this was due to the relatively small sample in the study. Such debilitating complications, however, can occur,
so one should always proceed with caution when attempting haemorrhoid ligation.

Since its introduction, haemorrhoid band ligation has been regarded as the most cost-effective modality available for the treatment of second- and third-degree haemorrhoids. This has been the main reason why it is widely used compared with other more costly modalities. Avoidance of the complications associated with rubber band ligation will further add to its cost advantage. Hence, the use of a single-operator vacuum suction apparatus, as shown by our small study, might assist in achieving this extra advantage.

In conclusion, rubber band ligation remains a simple, cost-effective and convenient modality in treating second- and third-degree haemorrhoids as an outpatient procedure. Comparison between the two available methods of rubber band ligation in our study has proven that suction band ligation is superior to forceps ligation for the treatment of second- and third-degree haemorrhoids in terms of pain tolerance, amount of analgesia consumed and intra-procedure bleeding. We now recommend the single-operator vacuum suction technique for rubber band ligation of haemorrhoids.

References